UNITED NATIONS

Food and Agriculture Organization of the United Nations

UNEP/FAO/RC/CRC.20/INF/54

Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Distr.: General
30 September 2024

English only

Chemical Review Committee
Twentieth meeting
Rome, 17–20 September 2024
Agenda item 4 (c)

Technical work: review of notifications of final regulatory action

Intersessional task group reports presented at the twentieth meeting of the Chemical Review Committee

Note by the Secretariat

The annex to the present note contains the intersessional task group reports on chlorpyrifos-methyl, dichlorvos, hexachlorobenzene, paraquat and paraquat dichloride, pentachlorobenzene, profenofos, cypermethrin emulsifiable concentrate 10%, cypermethrin emulsifiable concentrate 35%, emamectin benzoate water soluble granules 5% and methomyl soluble powder 40%, as prepared by the intersessional task groups and presented at the twentieth meeting of the Chemical Review Committee. The present note, including its annex, has not been formally edited.

Annex

Intersessional task group reports presented to the twentieth meeting of the Chemical Review Committee

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I. Task group report on chlorpyrifos-methyl

Rotterdam Convention

Twentieth Meeting of the Chemical Review Committee

Rome, 17–20 September 2024

Report of the task group on chlorpyrifos-methyl (notification from the European Union)

Task group members

Chair Saida Ech-Chayeb (Morocco)

Drafter Carles Escriva (Germany)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/9: Chlorpyrifos-methyl: notifications of final regulatory action

UNEP/FAO/RC/CRC.20/INF/15/Rev.1: Chlorpyrifos-methyl: supporting documentation provided by the European Union

UNEP/FAO/RC/CRC.20/INF/6: Information on trade

Handbook of working procedures and policy guidance for the Chemical Review Committee (October 2019)

Conclusion by the task group on the notifications of final regulatory action submitted by the European Union in respect of chlorpyrifos-methyl in the pesticide category

1. The notification on chlorpyrifos-methyl from the European Union has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. This notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.20/9, UNEP/FAO/RC/CRC.20/INF/15/Rev1. Information on trade was made available in document UNEP/FAO/RC/CRC.20/INF/6.

Tabular summary of findings of the task group:

Criteria	***European Union***
(a)	*Met*
(b) as a whole	*Met*
(b)(i)	*Met*
(b)(ii)	*Met*
(b)(iii)	*Met*
(c)(i)	*Met*
(c)(ii)	*Met*
(c)(iii)	*Met*
(c)(iv)	*Met*
(d)	*Met*

A. Scope of the regulatory action notified by the European Union

3. The regulatory action notified by the European Union relates to chlorpyrifos-methyl (CAS No. 5598-13-0) in the pesticide category.

4. The regulatory action is notified as a ban. It is prohibited to place on the market or use plant production products containing chlorpyrifos-methyl by the Commission Implementing Regulation (EU) 2020/17 dated 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of the plant products on the market, amending the Annex to Commission Implementing Regulation (EU) No. 540/2011 (Official Journal of the European Union L 7, 13.1.2020, p.11). EU Member States had to withdraw authorisations for plant protection products containing chlorpyrifos-methyl as an active substance by 16 February 2020. Disposal, storage, placing on the market and use of existing stocks of plant protection products containing chlorpyrifos-methyl is prohibited as of 16 April 2020.

5. The ban on chlorpyrifos-methyl was based on the evaluation of the hazards and risks to human health (UNEP/FAO/RC/CRC.20/9, annex, sect. 2.4. of the European Union's notification).

6. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

7. Before the final regulatory action chlorpyrifos-methyl was used as an insecticide. The pesticide formulations in the European Union were EMBAIXADOR 200 CS, METYLFOS 200 CS, SENTOSAN MAX, SUNDEK SMART, JARKAL 200 CS, SAP200CHLORI, GF-1684 and Reldan 22. (UNEP/FAO/RC/CRC.20/9, annex, sec.1.3 of the European Union's notification).

8. The notification states in section 2.4.1 that the ban of all uses of chlorpyrifos-methyl formulations was based on a hazard and risk assessment related to human health. In the final regulatory action, the following concerns were identified as a result of the chlorpyrifos-methyl assessment:

(a) It cannot be excluded that chlorpyrifos-methyl has a genotoxic potential. Consequently, it is not possible to establish health-based reference values for chlorpyrifos-methyl and to conduct the relevant consumer and non-dietary risk assessments.

(b) Furthermore, developmental neurotoxicity (DNT) effects were observed in rats and epidemiological evidence exists showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children.

(c) It is appropriate to classify chlorpyrifos as toxic for reproduction, category 1B.

9. Therefore, the task group concludes that the final regulatory action was taken in order to protect human health; accordingly, the criterion in paragraph (a) of Annex II is met.

C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

10. The overall conclusion of the assessment of chlorpyrifos-methyl in relation to impacts on human health, based on the information available and the proposed conditions of use and exposure conditions that prevail in the EU, is that the approval criteria are not satisfied as concerns were identified. The main areas of concern were the genotoxicity and the developmental neurotoxicity (DNT).

11. The genotoxic potential of chlorpyrifos-methyl could not be ruled out based on the information available. An in vitro study produced positive findings of chromosome aberration in the presence of rat liver metabolic activation system (S9) in Chinese hamster ovary (CHO). It was noted that there was no public literature available for chlorpyrifos-methyl with regard to the genotoxic potential, while several publications were available for chlorpyrifos instead. The experts discussed the structural similarity between chlorpyrifos and chlorpyrifos-methyl and since concerns were raised for chlorpyrifos with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition) a data gap was concluded to be present for chlorpyrifos-methyl. As a consequence, it could not be excluded that chlorpyrifos-methyl may have DNA damaging potential and therefore no toxicological reference values can be set.

12. As for the DNT, a study in rats was submitted where a significant decrease in the height of cerebral hemisphere on post-natal day (PND) 72 was observed in males at the top dose. The experts also discussed the epidemiological evidence showing associations between chlorpyrifos and chlorpyrifos-methyl exposure during neurodevelopment and adverse health effects (attention deficit/ hyperactivity disorders, decrease in intelligent quotient and working memory, etc.). In particular, three main birth cohort studies were considered. Using different biomarkers of exposure, these studies showed that prenatal exposure to organophosphates (OPs) produces a consistent pattern of early cognitive and behavioural deficits. The experts discussed also other epidemiological evidence from the public literature. The majority of the experts considered that the results from some of these studies contribute to the evidence of DNT effects in humans due to the exposure to chlorpyrifos and chlorpyrifos-methyl and occurring at doses lower than that causing 20% inhibition of AChE.

13. Taking into consideration the DNT study outcome (reduction in cerebellum height for chlorpyrifos), the epidemiological evidence showing an association between chlorpyrifos/chlorpyrifos-methyl exposure during development and neurodevelopmental outcomes, and the overall analysis of the published literature (in vivo, in vitro and human data), the experts indicated that chlorpyrifos-methyl, based on the available toxicological data set, may be expected to meet the criteria for classification as toxic for the reproduction, REPRO 1B, H360D ‘May damage the unborn child’.

14. The supporting documentation (UNEP/FAO/RC/CRC.20/INF/15/Rev1) contains the main results of the risk assessment. As a first step, the risk evaluation of the active substance chlorpyrifos-methyl was done by a rapporteur member State, taking into account proposed uses and exposure conditions that prevail in the EU. The rapporteur member State then submitted its renewal assessment

report (RAR) to the European Food Safety Authority (EFSA). EFSA organised an intensive consultation of technical experts from Member States, to review the RAR and the comments received thereon (peer review). EFSA also launched a public consultation on the RAR. After the commenting period for member States, the applicants and the public. in April 2019, the EFSA convened an expert discussion related to impacts on mammalian toxicology and human health. As a result, EFSA was mandated by the European Commission to prepare a statement on the outcome of the risk assessment for human health for chlorpyrifos-methyl, which was issued on 31 July 2019. In September 2019, EFSA convened a second expert meeting to further discuss the read-across approach between chlorpyrifos and chlorpyrifos-methyl that it indicated required further discussion in its statement of 31 July 2019. On 11 November 2019, EFSA sent to the Commission an updated statement on the outcomes of the risk assessment for human health for chlorpyrifos-methyl taking into account the outcome of the expert meeting held in September 2019. The concerns raised for chlorpyrifos with regard to chromosome aberration and DNA damage (oxidative stress and topoisomerase II inhibition) may apply to chlorpyrifos-methyl, resulting in an unclear genotoxicity potential. The DNT effects observed at the lowest dose tested in the DNT study with chlorpyrifos (decrease in cerebellum height corrected by brain weight), indicate a health concern. This outcome would be conservatively applied also to chlorpyrifos-methyl. Furthermore, the epidemiological evidence supports the developmental neurological outcomes in children for both chlorpyrifos and chlorpyrifos-methyl.

15. The experts determined that it was not possible to establish health-based reference values for chlorpyrifos-methyl or to conduct relevant consumer and non-dietary risk assessments. Therefore, the experts also determined that it cannot be excluded that there is a probability of adverse effects to human health at any level of exposure.

16. Summarizing the above, the final regulatory action was based on a hazard and risk evaluation to human health and the prevailing conditions of the use of chlorpyrifos-methyl pesticides in the European Union.

17. Based on the above, the task group confirms that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

18. Therefore, the task group concludes that the criteria in paragraph (b) of Annex II as a whole are met**.**

D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

19. The final regulatory action is a total ban of all uses of chlorpyrifos-methyl in plant protection products in the EU. Consequently, it is expected that the regulatory action will lead to a reduction of risk for human health from use of plants protection products containing chlorpyrifos-methyl in the EU.

20. Hence, the task group concludes that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

21. Since the final regulatory cancelled the registration and banned all applications of chlorpyrifos-methyl as a plant protection product, it can be expected that it led to a significant reduction of the health risk.

22. Hence, the task group concludes that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

23. The notification stated that the similar human health problems are likely to be encountered in other regions where chlorpyrifos-methyl is used, particularly in developing countries. In addition, there is no indication that the considerations that led to the final regulatory action are of limited applicability.

24. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

25. The European Union reported one notified export of chlorpyrifos-methyl to one country in 2023 (UNEP/FAO/RC/CRC.20/9, annex, sect. 2.5.1 of the European Union´s notification). Australia also reported ongoing international trade in chlorpyrifos-methyl (UNEP/FAO/RC/CRC.20/INF/6).

26. Therefore, the task group concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

27. The notification and the supporting documentation does not contain any indication on intentional misuse of chlorpyrifos-methyl in the European Union.

28. Therefore, the task group concludes that the criterion in paragraph (d) is met.

F. Conclusion

29. The task group concludes that the notification of final regulatory action by the European Union meets the criteria set out in Annex II to the Convention.

II. Task group report on dichlorvos

Rotterdam Convention

Twentieth Meeting of the Chemical Review Committee

Rome, 17–20 September 2024

Report of the task group on dichlorvos (notification from the European Union)

Task group members

Chair Saida Ech-Chayeb (Morocco)

Drafter Carles Escriva (Germany)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/11: Dichlorvos: notifications of final regulatory action

UNEP/FAO/RC/CRC.20/INF/18: Dichlorvos: supporting documentation provided by the European Union

UNEP/FAO/RC/CRC.20/INF/6: Information on trade

Handbook of working procedures and policy guidance for the Chemical Review Committee (October 2019)

Conclusion by the task group on the notification of final regulatory action submitted by the European Union in respect of dichlorvos in the pesticide category

1. The notification on dichlorvos from the European Union has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. This notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.20/11, UNEP/FAO/RC/CRC.20/INF/18. Information on trade was made available in document UNEP/FAO/RC/CRC.20/INF/6.

Tabular summary of findings of the task group:

Criteria	***European Union***
(a)	*Met*
(b) as a whole	Met
(b)(i)	*Met*
(b)(ii)	*Met*
(b)(iii)	Met
(c)(i)	*Met*
(c)(ii)	*Met*
(c)(iii)	*Met*
(c)(iv)	*Met*
(d)	*Met*

A. Scope of the regulatory action notified by European Union

3. The regulatory action notified by European Union relates to dichlorvos (CAS No. 62-73-7) in the pesticide category.

4. The regulatory action is notified as a severe restriction for the pesticide category, which originates as a ban for plant protection products. It is prohibited to be placed on the market or use plant production products containing dichlorvos by the Commission Decision 2007/387/EC dated 6 June 2007 concerning the non-inclusion of dichlorvos in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. Official Journal of the European Union, L 145, 6.6.2007, p.16. EU Member States had to withdraw authorisations for plant protection products containing dichlorvos as an active substance by 6 December 2007. From 7 June 2007, no authorisations for plant protection products containing dichlorvos could be granted or renewed.

5. At the time of the notification, dichlorvos was used as a biocidal product in the form of the product-type 18 – insecticides, acaricides and products to control other arthropods. This use remained allowed pursuant Directive 98/8/EC concerning the placing of biocidal products on the market.

6. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

7. Before the final regulatory action, dichlorvos was used mainly as a plant protection product, classified as an organophosphate acaricide and insecticide. The pesticide formulations in the European Union were Denkavepon, Vapona, Nuvan, Nogos and DDVP. (UNEP/FAO/RC/CRC.20/11, annex, sec.1.3 of the European Union's notification).

8. The notification states in section 2.4.1 that the ban on the use of dichlorvos as a plant protection product was based on a hazard and risk assessment related to human health. Such risk assessment was carried out on the basis of Directive 91/414/EEC, which provided for the European Commission to issue a programme of work for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I.

9. In the assessment, no acceptable risks for operators, workers and bystanders arising from the use of plant protection products containing dichlorvos could be demonstrated. Moreover, genotoxic and carcinogenic properties could also not be ruled out.

10. Therefore, the task group concludes that the final regulatory action was taken in order to protect human health; accordingly, the criterion in paragraph (a) of Annex II is met.

C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

11. The overall conclusion of the assessment of dichlorvos in relation to impacts on human health, based on the information available and the proposed conditions of use, is that the approval criteria are not satisfied as concerns were identified and that the information available is insufficient. The main areas of concern that triggered the final regulatory action were the acute toxicity and genotoxicity. As a further matter, the information available was insufficient to satisfy the requirements in particular with regard to lack of data on toxicity of breakdown products and a finalised assessment of operators, workers and bystanders' exposure (definitive reference values were not agreed on). The type of application scenario used in the EU assessment was room treatment for the protection of flower bulbs against thrips.

12. In relation to the acute toxicity, the assessment reported dichlorvos being toxic, following acute oral and dermal exposure (LD50 57 mg/ kg bw and 120 mg/kg bw, respectively). It is very toxic after acute inhalation exposure (LC50 0.083 mg/L). The following classification was also proposed: R25 "Toxic if swallowed", R26 "Very toxic by inhalation", R43 "May cause sensitization by skin contact".

13. As per the genotoxicity, a positive COMET assay in mouse keratinocytes after topical application obtained a positive result (this study was, nevertheless, a non-routine study, not widely used and not properly validated). In relation to the gene mutation assay in transgenic mice, it was noted that the dose levels used were sufficient to cause mortality. The mechanism of genotoxicity was considered to be methylation-mediated.

14. Regarding the mutagenicity of dichlorvos, it was concluded that it is an in-vitro mutagen and that there is limited evidence that it is an in-vivo contact mutagen. It was noted that although several of the studies show methodological deficiencies there is evidence that dichlorvos is a weak DNA alkylating agent. Thus, the issue of the mutagenic potential still remains not completely clear.

15. A question addressing the mutagenic and carcinogenic potential of dichlorvos was proposed to be forwarded to the EFSA PPR panel due to the weaknesses of data provided, not adequate to exclude carcinogenic activity. Therefore, the derivation of the reference doses including the safety factor, and accordingly the operator exposure calculations, was not considered appropriate until the outcome of the EFSA PPR panel discussions. The PPR opinion has been adopted on 1 April 2006. Taking the conclusions in the opinion into consideration, it was agreed at the meeting with member State representatives in April 2006 that the risk assessment is still inconclusive due to the uncertainties of the genotoxic and carcinogenic properties of dichlorvos also considering the overall poor quality of the dossier.

16. The supporting documentation (UNEP/FAO/RC/CRC.20/INF/18) contains the review report for the active substance dichlorvos conducted by EFSA. The EFSA organised an intensive consultation of technical experts from the member States to review the draft assessment report and the comments received thereon (peer review). The review report contains the conclusions of the final examination by the Standing Committee and considers the conclusion of the EFSA. The overall conclusion of this evaluation, based on the information available and the proposed conditions of use, is that: the information available was insufficient to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC and that concerns were identified with regard to the risk assessment which was considered to be inconclusive due to the uncertainties of the genotoxic and carcinogenic

properties of the substance. In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing dichlorvos was expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

17. As a conclusion of the risk assessment, it was determined that it was not possible to establish health-based reference values for dichlorvos. Therefore, it cannot be excluded that there is a probability of adverse effects to human health at any level of exposure.

18. Summarizing the above, the final regulatory action was based on a hazard and risk evaluation to human health and the prevailing conditions of the use of dichlorvos plant protection products in the European Union.

19. Based on the above, the task group confirms that the criteria in paragraph (b) (i), (ii) and (iii) of Annex II are met.

20. Therefore, the task group concludes that the criteria in paragraph (b) of Annex II as a whole are met.

D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

21. The final regulatory action banned the use of dichlorvos in plant protection products, it is expected that the regulatory action led to a significant reduction of the quantity of the chemical used.

22. Hence, the task group concludes that the criterion in paragraph (c) (i) is met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

23. Since the final regulatory cancelled the registration and banned all applications of dichlorvos as a plant protection product, it can be expected that it led to a significant reduction of risk for human health.

24. Hence, the task group concludes that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

25. The notification stated in section 2.5.2 that similar human health problems are likely to be encountered in other regions where dichlorvos is used, particularly in developing countries.

26. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

27. The Secretariat collected information on trade (UNEP/FAO/RC/CRC.19/INF/6). The received information from Brazil, Canada, Chile, EU and CropLife shows that there is evidence of ongoing international trade.

28. Therefore, the task group concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

29. The notification does not refer to the data of intentional misuses of dichlorvos in the European Union.

30. Therefore, the task group concludes that the criterion in paragraph (d) is met.

F. Conclusion

31. The task group concludes that the notification of final regulatory action by the European Union meets the criteria set out in Annex II to the Convention.

III. Task group report on hexachlorobenzene

Rotterdam Convention

Twentieth meeting of the Chemical Review Committee

Rome, Italy, 17–20 September 2024

Report of the task group on hexachlorobenzene (notification from Australia)

Task group members

Chair Ms. Victorine Pinas (Suriname)

Drafter Mr. Adam Barlow (Australia)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/14: Hexachlorobenzene: notification of final regulatory action

UNEP/FAO/RC/CRC.20/INF/26: Hexachlorobenzene: supporting documentation provided by Australia

UNEP/FAO/RC/CRC.20/INF/27: Hexachlorobenzene: notification from Canada reviewed by the Chemical Review Committee and the rationale for its conclusion

UNEP/FAO/RC/CRC.20/INF/6: Information on trade

Handbook of working procedures and policy guidance for the Chemical Review Committee (October 2019)

Conclusion by the task group on the notification of final regulatory action submitted by Australia in respect of hexachlorobenzene in the industrial category

1. The notification on hexachlorobenzene from Australia has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. This notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.20/14 and UNEP/FAO/RC/CRC.20/INF/26. Information on trade was made available in document UNEP/FAO/RC/CRC.20/INF/6.

Tabular summary of findings of the task group:

Criteria	***Australia***
(a)	*Met*
(b) as a whole	*Not met*
(b)(i)	*Met*
(b)(ii)	*Met*
(b)(iii)	*Not met*
(c)(i)	*Not met*
(c)(ii)	*Not met*
(c)(iii)	*Met*
(c)(iv)	*Not met*
(d)	*Met*

A. Scope of the regulatory action notified by Australia

3. The regulatory action notified by Australia relates to hexachlorobenzene (CAS No. 118-74-1) in the industrial category. Consistent with requirements under the Industrial Chemicals Act 2019, sections 95 and 159(2), the Executive Director of the Australian Industrial Chemicals Introduction Scheme (AICIS) declares that hexachlorobenzene (CAS No. 118-74-1) was removed from the Australian Inventory of Industrial Chemicals (AIIC). Removal from the AIIC introduces severe restrictions on the manufacture and use of the chemical in addition to the prohibition of import. Under Australian legislation this chemical is severely restricted as defined in the Rotterdam Convention.

4. Existing regulatory controls in place restrict the import of hexachlorobenzene, since 2004 its import is prohibited in accordance with Schedule 9 of the Customs (Prohibited Imports) Regulations 1956. Hexachlorobenzene was listed on the AIIC until February 2023, though the chemical is not manufactured or exported from Australia, while on the Inventory, the manufacture of the chemical as an industrial chemical was possible under the Industrial Chemicals Act 2019. State and territory environment protection regulators provide further restrictions within facility licensing and waste disposal frameworks.

5. As hexachlorobenzene has now been removed from the Inventory, it cannot be introduced under the ‘listed’ category. This has the effect of formalising severe restrictions placed on the introduction of the chemical into Australia.

6. The final regulatory action entered into force on 8 February 2023.

7. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

8. The risk evaluation attached to the notification identifies risks to both human health and the environment. The FRA is the proposed means of managing these risks.

9. Therefore, the task group concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

10. According to section 2.4.1 of the notification, a risk evaluation was conducted in accordance with established protocols under the Australian Industrial Chemicals Introduction Scheme. The risk evaluation is provided in the supporting information (UNEP/FAO/RC/CRC.20/INF/26). In the evaluation, the generation and analysis of data has been conducted according to scientific methods and international best practice. Data reviews have been performed and documented in accordance with generally recognized scientific principles and procedures. The evaluation cites several international reports and scientific journal articles as sources of information for establishing the human health and environment hazards and risks of the chemical. [Also, in section 2.3.2 it is stated that appropriate procedures and safety controls must be in place to eliminate or minimize the risks from the introduction to persons involved in the research and the environment.

11. The task group confirms that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

12. The risk evaluation presents and reviews hazard data that support its listing on the Stockholm Convention on Persistent Environmental Pollutants. The evaluation analyses available scientific hazard data as meeting the persistence, bioaccumulation, potential for long-range environmental transport, and potential for adverse effects criteria of Annex D of the Stockholm Convention. The potential human health effects reported were observations in various animal species following sub-chronic and chronic oral exposure to hexachlorobenzene have been associated with the liver, kidneys, ovary, and central nervous system. Other effects reported include skin lesions; alteration in porphyrin metabolism (porphyria); behavioural changes; altered thyroid functions and serum levels of thyroid hormones; renal effects; and changes in calcium homeostasis and bone morphometry. In animal studies, reproductive and developmental toxicity, and induction of cancer were reported following repeated exposure to hexachlorobenzene.

13. The risk evaluation analyses human and environmental exposure to hexachlorobenzene under the existing regulatory settings in Australia. Noting existing regulations prohibiting import and use of hexachlorobenzene, the assessed exposure routes include environmental and human exposure to hexachlorobenzene present as unintentional contaminants in certain chemical products, but that this exposure is expected to be low given very low reported concentrations in these products. Additional sources of exposure to the environment are also identified but do not contribute to the risk characterisation as they are non-industrial. It is noted that deliberate manufacture of hexachlorobenzene could considerably increase the volume of hexachlorobenzene released to the environment.

14. The risk evaluation also states that the chemical has been found in organisms across many environmental compartments and trophic levels and is highly bioaccumulative. This indicates a concern for chronic effects to predators and other high trophic level organisms that consume contaminated prey. Exposure to some mammalian predators and birds through diet indicate potential adverse reproductive effects at low to medium concentrations. The chemical also exhibits toxic effects to aquatic organisms over long term exposure timeframes.

15. The risk evaluation concludes that after ‘considering the human health and environmental effects of HCB and its fate in the environment identified in this Evaluation Statement, there are risks to the environment and potential risks to public and workers via secondary exposure from the environment, through introduction by manufacture, and the subsequent use of the chemical.’

16. The risk evaluation states that since the chemical is a persistent organic pollutant, there was significant long-term risks to the environment from the manufacture and use of the chemical, including from introduction in articles. While import of the chemical is prohibited under existing legislation, manufacture was not explicitly prohibited in Australia and, in principle, remains an authorised introduction whilst the chemical remains listed on the Inventory. While the risk evaluation concluded that there is low risk to human health (both workers and the public) and the environment from existing

introduction and use patterns and the chemicals presence as impurities in products and articles, it also concludes that this risk would increase should manufacture of hexachlorobenzene begin in Australia. The final regulatory action is made on the basis of risks to the environment and risks to public and workers via secondary exposure from the environment through introduction by manufacture and subsequent use of hexachlorobenzene.

17. However, the notification does not contain sufficient bridging information on the exposure of the chemical to human health and the environment in the notifying country to meet the requirements for the criteria in paragraph (b) (iii).

18. The task group confirms that the criteria in paragraph (b) (iii) of Annex II are not met.

19. Therefore, the task group concludes that the criteria in paragraph (b) of Annex II as a whole are not met**.**

D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

20. The notification states that hexachlorobenzene is not manufactured in, imported into or exported from Australia. The FRA is unlikely to lead to a significant decrease in the quantity of the chemical used or the number of its uses.

21. Hence, the task group concludes that the criterion in paragraph (c) (i) is not met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

22. The notification states that hexachlorobenzene is not manufactured in, imported into or exported from Australia. The expected effect of the final regulatory action is that it will prevent manufacture of the chemical in the future. Noting that no indications were given that hexachlorobenzene manufacture was expected to or would plausibly occur in Australia in the future, this action only prevents the existing risk from increasing, rather than leading to an actual reduction in risk.

23. Hence, the task group concludes that the criterion in paragraph (c) (ii) is not met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

24. Section 2.5.3.1 of the notification states that the final regulatory action will formalise the severe restriction of the introduction and use of hexachlorobenzene and will enhance legal clarity leading to the protection the health of workers and the public. These considerations are applicable to other geographical areas and are not limited in other circumstances.

25. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

26. The chemical is not expected to be present in international trade. The chemical is listed on Annex A of the Stockholm Convention and its production and use is prohibited globally. No international markets for this chemical are expected to exist.

27. Therefore, the task group concludes that the criterion in paragraph (c) (iv) is not met.

E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

28. There is no indication in the notification that consideration related to intentional misuse prompted the final regulatory action.

F. Conclusion

29. The task group concludes that the notification of final regulatory action by Australia does not meet the criteria set out in Annex II to the Convention.

IV. Task group report on paraquat and paraquat dichloride

Rotterdam Convention

Twentieth Meeting of the Chemical Review Committee

Rome, 17–20 September 2024

Report of the task group on paraquat and paraquat dichloride (notifications from Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal and Togo)

Task group members

Chair Saida Ech-Chayeb (Morocco)

Drafter Christian Bart (Canada)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/16: Paraquat and paraquat dichloride: notifications of final regulatory action

UNEP/FAO/RC/CRC.20/INF/29: Paraquat and paraquat dichloride: supporting documentation provided by Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal

UNEP/FAO/RC/CRC.20/INF/31: Paraquat and paraquat dichloride: supporting documentation provided by Togo

UNEP/FAO/RC/CRC.20/INF/6: Information on trade

Handbook of working procedures and policy guidance for the Chemical Review Committee (October 2019)

Conclusion by the task group on the notifications of final regulatory action submitted Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal and Togo in the pesticide category

1. The notifications on paraquat and paraquat dichloride from CILSS member countries (Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal) and Togo have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notifications appeared to meet the requirements of the Convention.

2. The notifications and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.20/16, UNEP/FAO/RC/CRC.20/INF/29 and UNEP/FAO/RC/CRC.20/INF/31. Information on trade was made available in document UNEP/FAO/RC/CRC.20/INF/6.

Tabular summary of findings of the task group:

Criteria	***CILSS member countries (Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger, Senegal)***	***Togo***
(a)	*Met*	*Met*
(b) as a whole	*Met*	*[Not Met]*
(b)(i)	*Met*	*Met*
(b)(ii)	*Met*	*Met*
(b)(iii)	*Met*	*[Not Met]*
(c)(i)	*Met*	*Met*
(c)(ii)	*Met*	*Met*
(c)(iii)	*Met*	*Met*
(c)(iv)	*Met*	*Met*
(d)	*Met*	*Met*

I. CILSS member countries

A. Scope of the regulatory action notified by CILSS member countries

3. The regulatory action notified by CILSS member countries (Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal) relates to paraquat and paraquat dichloride (CAS Nos. 4685-14-7 and 1910-42-5, respectively) in the pesticide category. Although the decision refer to paraquat, all notifications of final regulatory action relate to paraquat dichloride since paraquat generally is marketed as paraquat dichloride (EPA, 1997; Health Canada, 2006, UNEP/FAO/RC/CRC.20/INF/29).

4. The regulatory action is notified as a ban. The proposal to ban paraquat was put forward at the Sahelian Pesticide Committee (CSP) session held from 22 to 26 November 2010 and submitted for signature to the Coordinating Minister of CILSS. The Decision banning paraquat was signed by the Coordinating Minister of CILSS on 5 August 2011. A letter containing the decision to ban paraquat was sent to each holder of the provisional authorization for sale and to each applicant for a new approval. (section 2.2 of CILSS notification and UNEP/FAO/RC/CRC.20/INF/29).

5. The ban of use of paraquat and paraquat dichloride as of 5 August 2011 was based on risk to human health and the environment (section 3 of the CILSS notification and UNEP/FAO/RC/CRC.20/INF/29).

6. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

7. Before the final regulatory action, paraquat was used as a herbicide in cotton crops and maize (section 2.3.1 of the CILSS notification). Formulations authorized include Gramoxone Super, Gramoquat Super (paraquat chloride), Gramoxone, Calloxone, Benaxone, Gramoquat, etc (UNEP/FAO/RC/CRC.20/INF/29).

8. In the CILSS countries, GRAMOXONE SUPER (paraquat 200 g/l) was granted a provisional authorization for sale (VPA), valid for three years, issued in May 2000 and renewed in January 2004. The PARANET SUPER 200 SL (paraquat 200 g/l) and Gramuron (paraquat 100 g/l + diuron 300 g/l) had their application dossiers under review at September 2004 and July 2005 sessions respectively (INSAH, 2010). Since 2006, paraquat-based formulations are no longer registered by the Sahelian Pesticide Committee (UNEP/FAO/RC/CRC.20/16 and UNEP/FAO/RC/CRC.20/INF/29).

9. The notifications state that the final regulatory action was based on a risk or hazard evaluation in order to protect human health and environment (Section 2.4 of the CILSS notification). Hazard and risk evaluations undertaken by other countries and international organizations were reviewed with regards to toxicological and ecotoxicological data, as well as the hazard classification of paraquat

10. Therefore, the task group concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

11. With regard to human health, the main concerns are linked to the high acute toxicity and the risk of toxicity to users in Sahelian conditions, which is considered unacceptable. WHO classifies paraquat as Class II (moderately toxic) (Footprint, 2010, WHO, 2008). Some formulations are classified as Class Ib (this is the case of GRAMOXONE PLUS which is classified T+: very toxic by inhalation). The minimal lethal dose of paraquat in humans is approximately 35 mg/kg bw. Poisoning treatment is symptomatic and there is no antidote to date (Mégarbane, 2003). Signs and symptoms appearing following dermal contact are: dry and cracked hands, loss or horizontal protuberance of nails, ulceration and abrasion (Mégarbane, 2003; Reigart and Robert, 1999). A phase of hepatic cytolysis and acute renal failure may appear on the 12th hour after Contamination (Mégarbane, 2003).

12. The evaluation was also based on the study in Burkina Faso (Toe, 2010), which includes information on pesticide use and environment conditions in general, such as low utilization rate of PPEs, the use of surface water as drinking water for human and animals. This pilot study showed that paraquat poisonings are numerous and significant in Burkina Faso. Paraquat-based formulations (GRAMOXONE, CALLOXONE, GRAMOQUAT SUPER, BENAXONE) alone were responsible for 59 cases, which represents 20% of poisoning cases. A total of 922 cases of poisoning were reported in 42 health centers. However, there is insufficient information to indicate if these are intentional or unintentional poisonings. The pesticide formulation responsible for the poisoning and the circumstance of its occurrence had been identified only in 22 cases. Five (5) out of these 22 cases occurred during pesticide application and GRAMOXONE accounted for two (2) cases. In the particular case of the use of Paraquat-based formulations, the absence of an antidote specific to this product together with the lack of specialized training of physicians leads to an inadequate management of intoxication case (UNEP/FAO/RC/CRC.20/INF/29).

13. With regard to the environment concerns, the notification provides very general statements without details on hazard and exposure. Paraquat is non-mobile (Koc = 106). Therefore, it does not present a risk of contamination of surface water by runoff. It is very persistent in soil (TD50 = 3000 days). Moreover, it presents low risk of groundwater contamination (GUS = - 6.95). In conclusion, the substance is classified as Aquatic Acute 1 (H400) (M-factor = 1000) and Aquatic Chronic 1 (H410) (M-factor = 100), as in accordance with EU Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (EC) No. 1272/2008.

14. Based on the above, the task group concludes that the criteria in paragraph (b) (i), (ii) of Annex II are met.

15. The CILSS risk evaluation and supporting documentation provides limited bridging information and comparison with the risk assessments performed by other Parties/organisations. However, in the pilot study, the occurrence of two poisoning cases during application, the background of inadequate PPE usage, the absence of an antidote for paraquat, and the lack of specialized training for handling poisoning cases in Burkina Faso support that the final regulation action was based on a risk evaluation under prevailing conditions. Therefore, the task group concludes that the criterion in paragraph (b) (iii) of Annex II is met.

16. Therefore, the task group concludes that the criteria in paragraph (b) of Annex II as a whole is met.

D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

17. Since the final regulatory decision banned the use of all pesticides containing paraquat and paraquat dichloride (UNEP/FAO/RC/CRC.20/16), it can be expected that the regulatory action will lead to a significant reduction in the quantity of the chemical distributed and used in all CILSS member countries.

18. Hence, the task group concludes that the criterion in paragraph (c) (i) is met**.**

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

19. Since the final regulatory decision banned the use of all pesticides containing paraquat and paraquat dichloride (UNEP/FAO/RC/CRC.20/16), it can be expected that this will represent a significant reduction of the health and environmental risks.

20. Hence, the task group concludes that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

21. The notification states that paraquat could be used in other countries under similar conditions. In Africa, according to the Paraquat Information Centre on behalf of Syngenta Crop Protection AG (Paraquat Information Centre, 2010), GRAMOXONE was registered and sold as of May 2009 in 19 countries, including Cameroon, Ghana, and Nigeria, all neighbours of CILSS countries (UNEP/FAO/RC/CRC.20/INF/29). Therefore, the relevance is not limited to the notified countries, nor does the notification contain any indications that the applicability of the considerations that led to the final regulatory action has any limitations.

22. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

23. The CILSS notification reported that 25 440 and 1875 L. of paraquat product had been imported between 2007 and 2010 (UNEP/FAO/RC/CRC.20/16, Burkina Faso). In response to the Secretariat's request to provide information on ongoing international trade of candidate chemicals that will be considered at the twentieth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.20/INF/6, the European Union confirmed ongoing international trade in paraquat and paraquat dichloride.

24. Therefore, the task group concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

25. The final regulatory decision to ban of the use of paraquat and paraquat dichloride pesticides was based on risks to human health mainly and the environment. There is no indication that intentional misuse was a reason for banning paraquat and paraquat dichloride in the CILSS member countries.

26. Based on the above consideration, the task group concludes that the criterion in paragraph (d) is met**.**

F. Conclusion

27. The task group concludes that the notification of final regulatory action by CILSS member countries (Burkina Faso, Cabo Verde, Chad, Mali, Mauritania, Niger and Senegal) meets the criteria set out in Annex II to the Convention.

II. Togo

A. Scope of the regulatory action notified by Togo

28. The regulatory action notified by Togo relates to paraquat dichloride (CAS Nos. 4685-14-7) in the pesticide category

29. According to the notification, all products containing paraquat are banned due to their high toxicity potential to humans and the environment. They can only be used in agriculture after a special derogation obtained from the competent services of the Ministry of Agriculture. The same applies to their importation, marketing, distribution, use and sale in the country. The decision came into force on 1 January 2015 (UNEP/FAO/RC/CRC.20/16).

30. The Legal basis outlined in the notification:

(a) Law No. 96-007/PR of July 3, 1996 relating to protection of plants in Togo

(b) Regulation No. 007/2007/CM/UEMOA of April 6, 2007 relating to protection of plants, animals and food in WAEMU.

(c) Regulation C/REG.21/11/10 of November 2010 harmonizing the structural framework and operational rules in terms of health safety food, plants and animals in the ECOWAS region.

(d) Decision No. 125/COOR/2011 of August 5, 2011 prohibiting formulations based on paraquat within CILSS (Togo is a new member of CILSS): In CILSS member states, formulations based on paraquat are no longer authorized by the Sahelian pesticide committee since 2006. Any use of paraquat in the nine former CILSS countries (Burkina Faso, Cape Verde, Gambia, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad) and the three new countries of CILSS (Benin, Ivory Coast and Togo) was banned by Decision No. 125/COOR/2011 signed by the Coordinating Minister of CILSS on August 5, 2011.

31. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

32. Before the final regulatory action, paraquat dichloride (CAS 4685-14-7) was used in Togo as a non-selective broad-spectrum herbicide particularly for weed control before the planting crops, aquatic weeds, and weeds orchard herbs (section 2.3.1 of the Togo notification).

33. The notification states that the final regulatory action is based on a risk or hazard evaluation (section 2.4 of the Togo notification). The notification refers to the CILSS Decision No. 125/COOR/2011 of August 5, 2011. The date of entry into force of the final regulatory action is 1 January 2015 (section 2.2.3 of the Togo notification).

34. Therefore, the task group concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

35. The final regulatory action is taken in the category of pesticides and prohibits all uses and formulations of paraquat dichloride in plant protection products.

36. The notification states that the final regulatory action is based on a risk or hazard evaluation (section 2.4 of the Togo notification). The notification refers to the CILSS Decision No. 125/COOR/2011 of August 5, 2011. The date of entry into force of the final regulatory action is 1 January 2025 (section 2.2.3 of the Togo notification).

37. According to the notification and supporting documentation, paraquat dichloride is harmful because of its highly acute toxicity if swallowed, even at low dose. It is fatal by inhalation, toxic by dermal contact and by ingestion. It causes damage to organs when ingested through prolonged and repeated exposure, is fatal by inhalation and toxic by skin contact or ingestion. Paraquat dichloride has a high proven risk to cause serious effects on the organs following repeated exposure or from prolonged exposure. In addition, paraquat dichloride is found to be very toxic to aquatic organisms and causes harmful long-term effects. Paraquat-induced toxicity in rats was also demonstrated with degenerative lesions of the nervous system similar to those of Parkinson's disease. A study shows that paraquat, like other neurotoxicants such as lead or mercury, can even at low doses inhibit the development and functioning of the brain and spinal cord by blocking the division of stem cells of the central nervous system (Togo Notification and UNEP/FAO/RC/CRC.20/INF/31).

38. Based on the above, the task group concludes that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

39. However, the Togo risk evaluation and supporting documentation provides limited bridging information and comparison with the risk assessments performed by other Parties/organisations and very general statements without details on hazard and exposure. Therefore, the task group concludes that the criterion in paragraph (b) (iii) of Annex II is not met.

40. Therefore, the task group concludes that the criteria in paragraph (b) of Annex II as a whole is [not met].

D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

41. Since the final regulatory decision banned the use of all pesticides containing paraquat dichloride, it can be expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.

42. Hence, the task group concludes that the criterion in paragraph (c) (i) is met**.**

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

43. Since the final regulatory decision banned the use of paraquat dichloride, it can be expected to result into a significant reduction of the health and environmental risks.

44. Hence, the task group concludes that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

45. The notification refers to the CILSS decision as being relevant to other countries or regions where paraquat dichloride may be used under similar conditions. In addition, the notification does not contain any indication that the applicability of the considerations that led to the final regulatory action has any limitations.

46. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

47. The notification from Togo does not include quantities if paraquat dichloride imported or exported. In response to the Secretariat's request to provide information on ongoing international trade in chemicals that will be considered at the twentieth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.20/INF/6, the European Union confirmed ongoing international trade in paraquat and paraquat dichloride.

48. Therefore, the task group concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

49. The final regulatory decision to ban of the use of paraquat dichloride pesticides was based on risks to human health and the environment. There is no indication that intentional misuse was a reason for banning paraquat and paraquat dichloride in Togo.

50. Based on the above point, the task group concludes that the criterion in paragraph (d) is met**.**

F. Conclusion

51. The task group concludes that the notification of final regulatory action by Togo [does not meet] the criteria set out in Annex II to the Convention.

III. Conclusion

52. The task group concludes that the final regulatory action notifications from the group of CILSS Parties meets all the criteria set out in Annex II to the Convention and that the notification of final regulatory action by Togo [does not meet] the criteria set out in Annex II to the Convention.

V. Task group report on pentachlorobenzene

Rotterdam Convention

Twentieth meeting of the Chemical Review Committee

Rome, Italy, 17–20 September 2024

Report of the task group on pentachlorobenzene (notification from Australia)

Task group members

Chair Ms. Victorine Pinas (Suriname)

Drafter Mr. Adam Barlow (Australia)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/17: Pentachlorobenzene: notification of final regulatory action

UNEP/FAO/RC/CRC.20/INF/34: Pentachlorobenzene: supporting documentation provided by Australia

UNEP/FAO/RC/CRC.20/INF/35: Pentachlorobenzene: notification from Canada reviewed by the Chemical Review Committee and the rationale for its conclusion

UNEP/FAO/RC/CRC.20/INF/6: Information on trade

Handbook of working procedures and policy guidance for the Chemical Review Committee (October 2019)

Conclusion by the task group on the notification of final regulatory action submitted by Australia in respect of pentachlorobenzene in the industrial category

1. The notification on pentachlorobenzene from Australia has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. This notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.20/17 and UNEP/FAO/RC/CRC.20/INF/34. Information on trade was made available in document UNEP/FAO/RC/CRC.20/INF/6.

Tabular summary of findings of the task group:

Criteria	***Australia***
(a)	*Met*
(b) as a whole	*Not met*
(b)(i)	*Met*
(b)(ii)	*Met*
(b)(iii)	*Not met*
(c)(i)	*Not met*
(c)(ii)	*Not met*
(c)(iii)	*Met*
(c)(iv)	*Not met*
(d)	*Met*

A. Scope of the regulatory action notified by Australia

3. The regulatory action notified by Australia relates to pentachlorobenzene (CAS No. 680-93-5) in the industrial chemical category.

4. Consistent with requirements under the Industrial Chemicals Act 2019, sections 95 and 159(2), the Executive Director of the Australian Industrial Chemicals Introduction Scheme (AICIS) declared that pentachlorobenzene (CAS No. 608-93-5) removed from the Australian Inventory of Industrial Chemicals (AIIC). Removal from the AIIC introduces severe restrictions on the introduction and use of the chemical. Under Australian legislation this chemical is severely restricted as defined in the Rotterdam Convention.

5. The final regulatory action entered into force on 8 February 2023.

6. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

7. The regulatory action was taken to protect human health and the environment.

8. The risk evaluation provided in the supporting information document (UNEP/FAO/RC/CRC.20/INF/34) identifies risks to the environment and to human health through environmental exposure. The expected effect of the FRA is to prevent import, manufacture and use of the chemical as the means of managing these risks.

9. Therefore, the task group concludes that the final regulatory action was taken in order to protect human health and the environment; accordingly, the criterion in paragraph (a) of Annex II is met.

C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

10. According to section 2.4.1 of the notification, a risk evaluation was conducted in accordance with established protocols under the Australian Industrial Chemicals Introduction Scheme. The risk evaluation is provided in the supporting information (UNEP/FAO/RC/CRC.20/INF/34). In the evaluation, the generation and analysis of data has been conducted according to scientific methods and international best practice. Data reviews have been performed and documented in accordance with generally recognized scientific principles and procedures. The risk evaluation derives most of the hazard data from the Persistent Organic Review Committees Risk profile for pentachlorobenzene.

11. The task group confirms that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

12. The risk evaluation presents and reviews hazard data that supported its listing on the Stockholm Convention on Persistent Environmental Pollutants. The evaluation analyses available scientific hazard data and summarises the environmental hazards of the chemical as meeting the persistence, bioaccumulation, potential for long-range environmental transport, and potential for adverse effects criteria of Annex D of the Stockholm Convention. The critical health effect identified was the acute toxicity following oral exposure. Effects on the liver, kidneys, and central nervous system from oral exposure to pentachlorobenzene were identified in experimental animals. Repeated exposure to the chemical was linked to adverse effects on the liver and kidneys. Based on the data reviewed in the evaluation, pentachlorobenzene was classified as Acute Toxic 4 (H302), acute aquatic category 1 (H400) and chronic aquatic category 1 (H410) according to the Globally Harmonized System of Classification and Labelling of Chemicals.

13. The risk evaluation analyses human and environmental exposure to pentachlorobenzene under the prevailing conditions of introduction and use in Australia. According to supporting information, the manufacture of the chemical ceased in Australia in 1995 and its use as component of articles ceased in 1998. Historical uses of pentachlorobenzene in Australia include as a viscosity modifier in polychlorinated biphenyl (PCB) mixtures for dielectric and coolant fluids, flame retardant in plastics and textiles and an intermediate in the manufacture of other chemicals. The assessed exposure routes include environmental and human exposure to pentachlorobenzene present as contaminants in certain chemical products and from diffuse source emissions from old electrical equipment and products that contain this chemical. The chemical is not known to be currently used in Australia but the introduction and use of the chemical or its presence in articles could considerably increase the volume of pentachlorobenzene released to the environment.

14. The risk evaluation concludes that after ‘considering the human health and environmental effects of pentachlorobenzene and its fate in the environment identified in this Evaluation Statement, there are risks to the environment and potential risks to public and workers via secondary exposure from the environment, through introduction by import or manufacture, and the subsequent use of the chemical.’

15. The risk evaluation states that since the chemical is a persistent organic pollutant, there were significant long-term risks to the environment from the manufacture and use of the chemical, including from introduction in articles. Risks to human health by secondary exposure from the environment were also identified. The final regulatory action is made on the basis of risks to the environment and risks to public and workers via secondary exposure from the environment through manufacture, import and use of pentachlorobenzene.

16. However, the notification does not contain sufficient bridging information on the exposure of the chemical to human health and the environment in the notifying country to meet the requirements for the criteria in paragraph (b) (iii).

17. The task group confirms that the criterion in paragraph (b) (iii) of Annex II is not met.

18. Therefore, the task group concludes that the criteria in paragraph (b) of Annex II as a whole are not met**.**

D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

19. The notification states that there is no information on current introduction (import and manufacture) and use of the chemical in Australia. The manufacture of the chemical was reported to have ceased in 1995 and the use as component of articles ceased in 1998. The FRA is unlikely to lead to a significant decrease in the quantity of the chemical used or the number of its uses as the notification states that the chemical is not in active use in Australia.

20. Hence, the task group concludes that the criterion in paragraph (c) (i) is not met.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

21. The notification states that there is no information on current introduction (import and manufacture) and use of the chemical in Australia. The expected effect of the final regulatory action is that it will prevent introduction of the chemical in the future. No indications were given that pentachlorobenzene introduction was expected to or would occur in Australia in the future. This action only prevents the existing risk from increasing, rather than leading to an actual reduction in risk.

22. Hence, the task group concludes that the criterion in paragraph (c) (ii) is not met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

23. The FRA restricts the manufacture, import and use of pentachlorobenzene to prevent ongoing release of the chemical to the environment. These considerations are applicable to other geographical areas and are not limited in other circumstances.

24. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

25. The chemical is not expected to be present in international trade. The chemical is listed on Annex A of the Stockholm Convention and its production and use is prohibited globally. No exemptions to the Stockholm Convention prohibitions on production or use have been requested and as a result, no international markets for this chemical are expected to exist.

26. Therefore, the task group concludes that the criterion in paragraph (c) (iv) is not met.

E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

27. There is no indication in the notification that consideration related to intentional misuse prompted the final regulatory action.

F. Conclusion

28. The task group concludes that the notification of final regulatory action by Australia does not meet the criteria set out in Annex II to the Convention.

VI. Task group report on profenofos

Rotterdam Convention

Twentieth meeting of the Chemical Review Committee

Rome, 17–20 September 2024

Report of the task group on profenofos (notification from Malaysia)

Task group members

Chair Saida Ech-Chayeb (Morocco)

Drafter Christian Bart (Canada)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/19: Profenofos: notifications of final regulatory action

UNEP/FAO/RC/CRC.20/INF/38: Profenofos: supporting documentation provided by Malaysia

UNEP/FAO/RC/CRC.20/INF/6: Information on trade

Handbook of working procedures and policy guidance for the Chemical Review Committee (October 2019)

Conclusion by the task group on the notification of final regulatory action submitted by Malaysia in the pesticide category

1. The notification on profenofos from Malaysia has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. This notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.

2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.20/19 and UNEP/FAO/RC/CRC.20/INF/38. Information on trade was made available in document UNEP/FAO/RC/CRC.20/INF/6.

Tabular summary of findings of the task group:

Criteria	***Malaysia***
(a)	*Met*
(b) as a whole	*[Open]*
(b)(i)	*Met*
(b)(ii)	*Met*
(b)(iii)	*[Open]*
(c)(i)	*Met*
(c)(ii)	*Met*
(c)(iii)	*Met*
(c)(iv)	*Met*
(d)	*Met*

A. Scope of the regulatory action notified by Malaysia

3. The regulatory action notified by Malaysia relates to profenofos (CAS No.41198-08-7) in the pesticide category.

4. The use of profenofos as a pesticide was banned starting 1 January 2015. A circular was issued on 16 May 2014 informing on the termination of the registration of products containing profenofos. Registrants have been given a period from 1 July 2014 until 31 December 2014 for stock clearance in the market (section 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.20/INF/38).

5. The ban of products containing profenofos in Malaysia as of 1 January 2015 was based on consistent violations of maximum residue limits (MRLs), frequent detection of use not in accordance to labelled directions and availability of suitable safer alternatives (section 2.5.3.3 of the Malaysia notification and UNEP/FAO/RC/CRC.20/INF/38).

6. This ban was enforced to all import, export, manufacture, use and sale except for limited amount for research and education purpose subject to approval by the Pesticide Board Malaysia. (section 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.20/INF/38).

7. The notification was found to meet the information requirements of Annex I.

B. Annex II paragraph (a) criterion

(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;

8. Before the final regulatory action, profenofos had been used in Malaysia as an insecticide to control thrips, mites and wide range of chewing and sucking insects in crops such as brassica, legumes, vegetables, fruits vegetable, ornamental plants and tobacco. The notification covers the following formulations: ELOCRON 500, CLOUT 45, CLEAVER 45.0 EC, ELAK 45 EC, FENOP, SERON, VEGECRON, KENSELEC, ASICON 45EC, PRESS, SULIRON 45EC, DEFOE 45EC, SELECRON 500 EC, GETTY 45EC, HEXTAR PROFENOFOS TECH 90 (sections 1.3 and 2.3.3 of the Malaysia notification). The recommendation of use on vegetables was removed on product labels in 2004 and the use on ornamental plants was gradually removed from the labels due to constant violation of the MRLs (section 2.3.1. of the Malaysia notification and UNEP/FAO/RC/CRC.20/INF/38).

9. The notification indicates that the final regulatory action was not based on a risk or hazard evaluation (section 2.4 of the Malaysia notification). The reason for the final regulatory action is based on consistent violations of MRLs, frequent detection of use not in accordance with labelled directions and availability of suitable safer alternatives (section 2.5.3.3 of the Malaysia notification).

10. Considering the toxicity profile of profenofos and repeated MRL violations included in the review form of Malaysia, the supporting documentation indicates that a strong case can be made for the complete deregistration of these pesticides to safeguard both the environment and public health (UNEP/FAO/RC/CRC.20/INF/38).

11. Therefore, the task group concludes that the final regulatory action was taken in order to protect human health; accordingly, the criterion in paragraph (a) of Annex II is met.

C. Annex II paragraph (b) criteria

(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;

12. The notification states that the final regulatory action was not based on a risk evaluation to protect human health (section 2.4 of the Malaysia notification). The scope of the review considered general facts on five organophosphate pesticides, including profenofos. The documents include information on toxicological and ecotoxicological properties, environmental behaviour and fate, as well and alternative pesticides (section 3 of the Malaysia notification and UNEP/FAO/RC/CRC.20/INF/38). The Pesticides Board reviewed and scrutinized many research information documents and publications related to profenofos (UNEP/FAO/RC/CRC.20/INF/38).

13. The following topics were covered by the profenofos pesticide review:

(a) Physico-chemical, toxicological and ecotoxicological information, environmental behaviour and fate;

(b) Trade difficulties associated with incompatibility of MRLs between Malaysia and major export destinations;

(c) Evaluation of available alternatives.

14. According to the supporting documentation, after 9 years of monitoring through pesticide residue monitoring activities by the Department of Agriculture of Malaysia and the 'Enhanced Enforcement Programme' (EEP) by the Government of Singapore, violations of pesticide residues on food crops still occur. This clearly shows that this pesticide has not been used according to the recommendations found on the label and contrary to good agricultural practices in local conditions.

15. Products containing profenofos are used solely for agricultural applications as a foliar spray. Several insecticides are used to control the same spectrum of pests for which the pesticides under review are recommended. Thus, there appear to be a sufficient number of alternatives to this pesticide for the control of insect pests in vegetables and crops.

16. In light of the above, the Pesticide Board considered proposing the complete deregistration of profenofos for the following reasons:

(a) Repeated Residue Problems: The pesticides have caused recurring residue problems in vegetable crops, violating MRLs and posing a potential risk to consumers.

(b) Failure of Good Agriculture Practices: Despite awareness efforts, farmers have not been able to adhere to GAP based on label recommendations, leading to the persistence of residue issues.

(c) Specificity to Vegetable Crops: The issues seem to be specific to vegetable crops, indicating a possible correlation between the pesticides and the types of crops affected.

(d) Toxicity concern: Profenofos is classified as moderately hazardous (WHO Class II).

(e) Potential Health Risks: Given the repeated violations of MRLs and the toxicity profile of the pesticides included in the review, which included profenofos, there is significant health risks associated with their use on crops over the long period of time.

17. Summarizing the above, the final regulatory action was based on consistent violations of MRLs, frequent detection of use not in accordance to labelled directions and availability of suitable alternatives.

18. Based on the above, the task group concludes that the criteria in paragraph (b) (i), (ii) of Annex II are met.

19. The notification states that the final regulatory action was not based on a risk evaluation to protect human health. However, the fact that profenofos residues in Malaysian agricultural products were found to exceed the corresponding MRLs may be considered as a risk evaluation. Although the value of an MRL is not in itself a toxicological value (e.g., acute reference dose, acceptable daily intake or equivalent), the excess does give an indication of potentially occurring health risks for consumers. Based on these considerations, the task group concludes that the criterion in paragraph (b) (iii) of Annex II is [open].

20. Therefore, the task group concludes that the criteria in paragraph (b) of Annex II as a whole is [open].

D. Annex II paragraph (c) criteria

(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

21. Malaysia reported significant quantities of profenofos imported between 1998 and 2001 (UNEP/FAO/RC/CRC.20/INF/38). Malaysia last imported 83.86 MT (Metric Tons) of profenofos in 2011 and 2012, respectively (section 2.5.1 of the Malaysia notification). In addition, the ban was enforced to all imports, exports, manufacture, use and sale, except for limited amount for research and education purposes subject to approval by the Pesticide Board of Malaysia. (section 2.2 of the Malaysia notification and UNEP/FAO/RC/CRC.20/INF/38). Consequently, it is expected that the regulatory action will lead to a significant reduction of the quantity of the chemical used.

22. Hence, the task group concludes that the criterion in paragraph (c) (i) is met**.**

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

23. Considering the toxicity profile of profenofos and repeated MRL violations included in the review from Malaysia, the final regulatory action to cancel the registration and ban the use of all pesticides containing profenofos is expected to result in a significant reduction of the risk to public health and the environment.

24. Hence, the task group concludes that the criterion in paragraph (c) (ii) is met.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

25. The supporting documentation (UNEP/FAO/RC/CRC.20/INF/38) indicates that Malaysia considered information from different countries and regions that was found to be relevant to Malaysia. There is no indication in the notification and the supporting documentation that the applicability of considerations is limited. Therefore, the same concerns may be considered relevant for countries with similar conditions.

26. Therefore, the task group concludes that the criterion in paragraph (c) (iii) is met.

(iv) Whether there is evidence of ongoing international trade in the chemical;

27. Malaysia last imported 83.86 MT of profenofos in 2012 (section 2.5.1 if the Malaysia notification). In response to the Secretariat's request to provide information on ongoing international trade of chemicals that will be considered at the twentieth meeting of the Chemicals Review Committee, UNEP/FAO/RC/CRC.20/INF/6, Brazil and Chile confirmed ongoing international trade in profenofos.

28. Therefore, the task group concludes that the criterion in paragraph (c) (iv) is met.

E. Annex II paragraph (d) criterion

(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

29. The Malaysian Pesticides Board's decision to ban the use of profenofos pesticides in the agricultural sector was based on the factors of consistent violations of MRLs, frequent detection of use not in accordance to labelled directions and availability of suitable safer and effective alternatives. Consequently, intentional misuse was not a reason for banning the use of products containing profenofos.

30. Based on the above considerations, the task group concludes that the criterion in paragraph (d) is met**.**

F. Conclusion

31. The task group concludes that the notification of final regulatory action by Malaysia is [open] with regard to the criteria set out in Annex II to the Convention.

VII. Task group report on cypermethrin emulsifiable concentrate 10%

Rotterdam Convention

Twentieth meeting of the Chemical Review Committee

Rome, Italy, 17–20 September 2024

Report of the task group on cypermethrin emulsifiable concentrate 10%

Task group members

Chair Suzana Andrejevic Stefanovic (Serbia)

Drafter Irene Beate Sørvik Malme (Norway)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/24: Cypermethrin emulsifiable concentrate 10%

UNEP/FAO/RC/CRC.20/INF/47: Cypermethrin emulsifiable concentrate 10%: information collected by the Secretariat

Introduction

1. A proposal from the Lao People's Democratic Republic to list cypermethrin emulsifiable concentrate 10% in Annex III to the Convention as a severely hazardous pesticide formulation was available to the Committee together with supporting documentation from this country. The proposal has undergone an initial review by the Secretariat, who concluded that the proposal did appear to meet the information requirements of part I of Annex IV to the Convention (UNEP/FAO/RC/CRC.20/24).

2. As laid down in Article 6 of the Convention, the Secretariat forwarded a summary of the information received to all parties and collected additional information as specified in part 2 of Annex IV. This information is available in documents UNEP/FAO/RC/CRC.20/INF/47.

3. The purpose of this report is to present the task group’s analysis of the proposal from the Lao People's Democratic Republic together with the supporting documentation for the Committee’s consideration.

4. The report includes a summary of the background of the proposal, a summary of the documentation required according to Annex IV, part 1, a summary of the availability of information that was collected by the Secretariat according to part 2 of Annex IV (tabular format) and an analysis of compatibility with the criteria of Annex IV part 3 (tabular summary and detailed analysis).

5. The report contains an overall analysis.

I. Analysis of the proposal from the Lao People's Democratic Republic

A. Background of the proposal

6. Within the Rotterdam Convention project on monitoring pesticide survey on Highly Hazardous Pesticides (HHPs) and Severely Hazardous Pesticides (SHPFs) conducted in Lao People's Democratic Republic (Lao PDR) in the period from January 2019 to May 2020, a field monitoring survey was carried out in 25 villages of 10 districts in three provinces in June-July 2019. A total of 169 farmers participated. The farmers from the survey were predominately males and most had a secondary/high school level education.

7. All pesticides produced, imported, exported, distributed and used in Lao PDR, must be registered with the Department of Agriculture, Ministry of Agriculture and Forestry, in accordance with Regulation on the Control of Pesticides in Lao PDR (No. 2860/MAF, Vientiane Capital, dated 11 Jun 2010). The survey showed, however, that the use of illegal pesticide products is widespread and that pesticides illegally imported and bought from unlicensed shops are still a common practice in the provinces. Also, the use of banned products is a problem in Lao PDR.

8. A total of 40 pesticide products were used by the farmers (active ingredients of different product names i.e. 22 insecticides, 12 herbicides and 6 fungicides), but only four of these products were registered with label in Lao language. The rest of the 36 products were illegally traded unregistered or banned pesticides with labels in foreign language i.e. Thai, Vietnamese and others.

9. Farmers reported a range of poisoning symptoms due to pesticide exposure. Some of the symptoms were very generic in nature while others were typical symptoms of pesticide poisoning. Lao PDR does not have a reporting system for incidents of pesticide poisoning. Three of these incidents were reported to be caused by using one of the unregistered products Super PHONEWDOL 10 labelled in Thai (cypermethrin 10% EC), a synthetic pyrethroid insecticide. The product was used with a hand-held battery-operated sprayer at a dose of 15 to 30 ml/20L of water. For two of the incidents, adverse effects reported were itchiness of the skin and excessive sweating after application in the field for half day period on maize and cucumber. One of these incidents was treated with medicine from a pharmacy. For the third incident, mixing/loading and spraying application for > 4 hours in watermelon caused insomnia, excessive sweating and cough. In all three incidents the operators were male, aged between 20 to 60 years, using protective clothing comprising gloves, boots/shoes, long-sleeve shirt and long pants. The symptoms occurred within 4-12 hours after using the pesticide.

10. The field monitoring survey reported that in cases of serious poisonings, farmers would seek medical treatment from the government hospital whereas some farmers treated the poisonings by traditional means (drinking lemon grass tea, sniffing out ants, taking a long rest etc.).

11. The use of full Personal Protective Equipment (PPE) among farmers during pesticide handling application is not common, due to hot weather and unavailability of these items at affordable cost. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers in small plantation areas, but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying.

12. The result of the implementation of the Rotterdam Convention project on monitoring pesticide survey on HHPs and SHPFs from January 2019 to May 2020 concluded that the dissemination of the decrees and legislation related to pesticide management has not been widely distributed in Lao PDR and that the accessibility of information related to pesticide rules and regulations is still limited. There is also little awareness and technical knowledge of the selection and application of pesticides among farmers. The country still does not have legal backing for taking action against illegal pesticide smuggling.

13. As a result of the monitoring pesticide survey Super PHONEWDOL 10 was identified as a SHPF by Lao PDR and consequently, the Lao PDR submitted a proposal to list cypermethrin 10% emulsifiable concentrate in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

B. Summary of information provided in the proposal and analysis of its compatibility with requirements of Annex IV

Information and criteria for listing severely hazardous pesticide formulations in Annex III

1. Part 1. Documentation required from a proposing Party

(PIC Circular LVI (56) – December 2022)

(a) Name of the hazardous pesticide formulation: Cypermethrin 10% EC

(b) Name of the active ingredient or ingredients in the formulation: Cypermethrin

(c) Relative amount of each active ingredient in the formulation: 10%

(d) Type of formulation: Emulsifiable Concentrate

(e) Trade names and name of producers, if available: Super PHONEWDOL 10

(f) Common and recognized patterns of use of the formulation within the proposing Party:

14. The formulation is not registered in Lao PDR; hence no use was permitted. The monitoring field survey of 2019 collected information on the usage of cypermethrin 10% EC. In three occasions, the product was applied using hand-held sprayer at a dose of 15 to 30 ml/20L of water for mixing/loading and spraying application in watermelon and for application in the field on maize or cucumber. The farmers used gloves, boots, long-sleeve shirt, long pants and simple hat as PPE.

15. The field monitoring survey of 2019 describes the common and recognized pesticide application practices in the field in the Lao PDR, such as the use of illegally traded unregistered or banned pesticides with labels in foreign language (90% of the pesticides in the survey), as well as the use of partial PPE by the farmers during pesticide handling due to the high temperature or unavailability of PPE at affordable cost. The surveyed farmers reported a range of poisoning symptoms due to pesticide exposure, where some of the symptoms were very generic in nature while others were typical symptoms of pesticides poisonings.

(g) A clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used:

16. The survey in 2019 collected details on three incidents relating to Super PHONEWDOL 10. The incidents relating to Super PHONEWDOL 10 can be summarized as follows: The incidents occurred after spraying the pesticide in fields where watermelon, maize or cucumber was grown. The product was applied using hand-held sprayer at a dose of 15 to 30 ml/20L of water. The label of the pesticide formulation (in Thai) contains information on the use (use in households), dosage (100 ml/2.5 l water, then spray 2.5 ml per 1 m^2) and use of PPE (use of gloves and mask during handling of pesticide). The frequency of application is from 2 to 5 times per crop season. Symptoms occurred in 4-12 hours after exposure as excessive sweating, itchiness of the skin, cough and insomnia. The route of exposure was through skin and/or inhalation during the use of the pesticide for more than 4 hours to half a day. Partial protective equipment such as gloves, boots, long-sleeve shirts, long pants and simple hats were used. No information is available on the date or year of the incidents.

(h) Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents:

17. Lao People's Democratic Republic does not have an incident reporting system for pesticide poisoning.

18. Lao PDR decided on national risk reduction measures (legislative and non-legislative measures) as a follow up from the monitoring survey:

(a) Legislative measures:

(i) Disseminate related legislations to pesticide investors and users;

(ii) Disseminate the implementation of Rotterdam Convention to all related stakeholders; monitor the importers of pesticides by checking authorization licenses, import permits and registration certificates, records of distribution and other requirements and encourage to import tools and plant protection equipment;

(iii) Inspect regularly retailer’s shops of pesticides by checking related licenses, labelling, and record of buying and selling;

(iv) Continue to monitor pesticide use in field by extending areas and add more type of crops especially crops for export;

(v) Technique of pesticide disposal.

(b) Non-legislative measures:

(i) Strengthen training and education system on effective and judicious use of pesticide among farmers;

(ii) Disseminate related pesticide legislation for improving pesticide management system;

(iii) Train on pesticide management for pesticide inspectors at district level, taskforce team, pesticide investors, and users including pesticide applicators services;

(iv) Strengthening pesticide inspectors on updating technical knowledge related to pesticide;

(v) Training more on HHPs and SHPFs before carrying out to monitor pesticide survey;

(vi) Disseminate the implementation of RC to all related stakeholders;

(vii) Update knowledge and continue to set up pesticide inspectors at provincial and district level throughout the country;

(viii) Establish network and national database on pesticide management.

19. Current legal infrastructure/admin procedure:

(a) Ministerial Decision on Registration of Pesticides in Lao PDR No. 3604/MAF, dated 17 Sep 2019 (improvement registration scheme and advice pesticide investors to follow the decision of Registration Unit of DOA);

(b) Ministerial Decision on Using Uniform and Insignia of Pesticide Inspector No. 1232/MAF, dated 23 April 2019 (dissemination and preparation of model uniform and insignia for pesticide inspector);

(c) Ministerial Instruction on Establishment and responsibilities of Taskforce team to inspect and apply the measures to violation pesticide legislation 0278/MAF, dated 19 Feb 2020;

(d) Ministerial Decision on Control of Pesticide Businesses No.0238/MAF, dated 14 Feb 2019.

2. Part 2. Information to be collected by the Secretariat

Part 2. Information to be collected by the Secretariat		
Type of information	**Information available?**	**Documentation in:**
(a) The physico-chemical, toxicological and ecotoxicological properties of the formulation;	Yes	Information was provided by the following Parties: Australia, Canada, Brazil, Chile, European Union, Kuwait, New Zealand, Norway, Oman, and Switzerland (in document UNEP/FAO/RC/CRC.20/INF/47)
(b) The existence of handling or applicator restrictions in other States;	Yes	
(c) Information on incidents related to the formulation in other States;	Yes	
(d) Information submitted by other Parties, international organizations, nongovernmental organizations or other relevant sources, whether national or international;	Yes	
(e) Risk and/or hazard evaluations, where available;	Yes	
(f) Indications, if available, of the extent of use of the formulation, such as the number of registrations or production or sales quantity;	Yes	

Part 2. Information to be collected by the Secretariat		
Type of information	**Information available?**	**Documentation in:**
(g) Other formulations of the pesticide in question, and incidents, if any, relating to these formulations;	Yes	
(h) Alternative pest-control practices;	Yes	
(i) Other information which the Chemical Review Committee may identify as relevant.	Yes	

3. Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III

Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III	
Criteria	**Criterion met?**
(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;	Met
(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;	Met
(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;	Met
(d) The significance of reported effects in relation to the quantity of the formulation used;	Met
(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.	Met

Compatibility with the criteria of Annex IV, part 3 - detailed argumentation

In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:

(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;

20. In Lao PDR, the field monitoring survey on pesticide practices conducted in 2019 revealed that the use of unregistered pesticides is very widespread: 36 of the pesticides recorded during the survey were unregistered pesticides while only 4 products were registered with label in Lao language. All the 36 unregistered pesticides were foreign products illegally sold in the country and the majority of them originated from Thailand (27 products), Vietnam (7 products) and from other countries (2 products). This illegal placing on the market is possible because legal action cannot be taken against violators, since related rules/regulations not being implemented at the time of the survey. Cypermethrin, which is not registered in Lao PDR, was among the common insecticides used in the country. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers with 20 L capacity in small plantation areas (0.2-0.3 ha), but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying. All of the 169 farmers interviewed used only minimum PPE (long-sleeved shirt, long pants, head cover, face cover and shoes). The use of full PPE like coverall, eye protection, mask with filter etc., among farmers during pesticide handling is not common, due to hot weather and unavailability of these items at affordable cost.

21. One of the challenges faced by the surveyed farmers were the difficulty of recalling the pesticide formulations that has caused the poisonings they suffered. This was further complicated if more than one pesticide were used at same time. Thus, 22 of the respondents reported that they had experienced some adverse effects from using certain pesticides. Still only 20 recalled the symptoms and only eight of them recalled precisely which particular pesticide product was responsible for the symptoms they suffered from. In contrast, 12 other farmers only reported that cumulative poisoning symptoms occurred and the list of the pesticide products they used at that particular time. The use of certain pesticide formulations under local conditions has caused adverse effects to the farmers.

22. The 2019 survey collected details for three incidents relating to **Super PHONEWDOL 10** (cypermethrin 10% EC), as follows: The frequency of application was 2-5 times per crop per season. All operators (male age 20-60 years) used gloves, boots/shoes, long sleeve shirt, long pants and simple hat. The label instructed to use masks and gloves when using the product. Masks and coveralls were not used, which can result in exposure through inhalation and skin when using hand-held sprayer. The type of gloves used is not specified (e.g., chemical resistant gloves). The duration of symptoms occurrence after exposure was not specified per incident. The date/year of the incidents is not stated.

23. **Incident one:** spraying the pesticide with a hand-held sprayer in the field on maize and cucumber with a dose of 30 ml/20L water. The duration of exposure was ½ day. Adverse effects occurred after 4-12 hours of the use were itchiness of the skin and excessive sweating. The route of exposure was skin and inhalation. Treatment: bought medicine in pharmacy. The type of medical treatment was not specified.

24. **Incident two:** spraying the pesticide with a hand-held sprayer in the field on maize and cucumber with a dose of 30 ml/20L water. The duration of exposure was ½ day. Adverse effects occurred after 4-12 hours after the use were itchiness of the skin and excessive sweating. The route of exposure was skin and inhalation. No treatment was given.

25. **Incident three:** the activities were mixing/loading and spraying the pesticide with a hand-held sprayer in the field on watermelon with a dose 15 ml/20L water. The duration of exposure was > 4 hours. Adverse effects occurred after less than 4 hours were insomnia, excessive sweating and cough. Route of exposure was inhalation. No treatment was given.

26. The evidence indicating that the use of **Super PHONEWDOL 10** (cypermethrin 10% EC), in accordance with common and recognized practices within Lao PDR, resulted in the reported incidents can be considered reliable with certain limitations (e.g. date/year of incident).

27. Based on the above, this criterion appears to be met.

(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

28. Documentation was made available to the CRC (UNEP/FAO/RC/CRC.20/INF/47) indicating that the above listed conditions for Lao PDR are similar to the conditions prevailing in other neighbouring States.

29. The same or similar formulations are used as pesticides or biocides (EU) in other countries with a similar climate and conditions. **Information was received from Australia, Brazil, Canada, Chile, the European Union, including Germany, Spain, Lithuania, the Netherlands, Portugal and Sweden, Kuwait, New Zealand, Norway, Oman and Switzerland.**

30. A summary of the available documentation regarding use of cypermethrin formulations, is presented below.

31. **Australia:** there are no registered products with 10% active concentration, and product specific handling or applicator restrictions in Australia; the number of similar registered products with the a.i. cypermethrin (**any formulation)** is 116.

32. **Brazil:** there are 24 formulated products containing cypermethrin in Brazil. A formulation based on 10% cypermethrin is not registered. Cypermethrin is a product widely used in Brazil for various crops, including: “cotton, peanuts, rice, potatoes, sweet potatoes, yacon potatoes, beets, coffee, yams, carrots, citrus fruits, peas, beans, beans, chickpeas, yams, lentils, cassava, parsley, millet, corn, soybeans, sorghum and tomatoes. The product is a pyrethroid insecticide that acts through contact and ingestion on indicated biological targets which cause considerable damage to the production of the indicated crops. Currently, approximately 5.6 million hectares are treated with products formulated with cypermethrin, acting mainly on caterpillars, bedbugs, kitties and leafhoppers”.

33. **Canada**: the formulations based on 10% cypermethrin emulsifiable concentrates are not registered in Canada. The following products are registered in Canada with the same or higher concentrations, and similar formulation types to the proposed formulation: emulsifiable concentrate 407 g/L - two products (registration numbers 15738 and 30316) and 250 g/L – two products (registration numbers 28795 and 32563).

34. Based on the results of the risk assessment, use restrictions were included on the label to minimize the exposure to cypermethrin. Canadian handling and applicator restrictions are detailed on labels of registered Canadian products. The re-evaluation decision for cypermethrin required amendments to those handling and applicator restrictions, which are reflected on current Canadian product labels:

35. To protect mixer/loader/applicators, the following statements are proposed to be added to all agricultural product labels:

(a) Wear long-sleeved shirt, long pants and chemical-resistant gloves during mixing, loading, application, clean up and repair. In addition, wear goggles or face shield during mixing and loading;

(b) For mechanically pressurized handgun (MPHG) application to strawberry: Wear coveralls (over single layer of clothes) and chemical-resistant gloves during mixing, loading and application.

36. To protect workers entering treated sites, modified restricted-entry intervals (REI) must be added to all agricultural labels. Products containing cypermethrin are unlikely to affect your health when used according to the proposed label directions.

37. The re-evaluation decision further includes label amendments for products containing cypermethrin: The following statement is to be added to the labels of technical grade cypermethrin under the section entitled "Toxicological Information":

Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically.

38. No registered applications have been identified for watermelon and cucumber (detected unregistered uses in Lao's PDR).

39. **Chile:** there are two pesticide formulations based on cypermethrin with current registration, there is no information on existence of restrictions on manipulation or application in Chile.

40. **European Union:** cypermethrin is approved for use as plant protection products and is classified as candidate for substitution. There are particular conditions to be taken into account by Member States in relation to the granting of plant protections products containing cypermethrin. Accordingly, the Review Report includes a list of restrictions that "Member States shall pay particular attention to:

(a) the protection of aquatic organisms, non-target arthropods, including bees;

(b) the consumer risk assessment;

(c) the technical specification of the active substance used in plant protection products.

41. As pesticides for use in biocidal products, cypermethrin has been approved in the product type 08 (wood preservatives) and products type 18 (insecticides) and has 70 authorized biocidal products in the EU in the product type 08 (wood preservatives). Information on the intrinsic properties of the substance, and the risk assessments performed on the active substances and the risk mitigation measures are also available.

42. Cypermethrin was not considered as skin irritant in the EU evaluation.

43. **Germany:** the active substance cypermethrin is approved at EU level for use in plant protection products (PPP). After approval of an active substance, national authorisations of the formulated PPP must be granted before placing PPP on the market. PPPs with cypermethrin are currently authorised in almost all EU Member States. PPP with the active substance cypermethrin have been authorised in Germany since 1978. As of October 2023, five different PPP with cypermethrin are authorised. 68 poisoning cases involving cypermethrin are recorded in the German national register on human poisonings with chemicals. No poisonings of vertebrates with cypermethrin have been recorded in the German national register. Information on risk reduction measures is available (in German).

44. The following product is registered with the same concentration SHERPA DUO 100 g/L EC (registration number 00A031-00) in Germany.

45. **Spain:** there are pesticide products authorized as biocides and also as plant protection products that contain cypermethrin. As pesticides for use in agriculture, there are 19 products authorised that contain cypermethrin. As biocides, there are still two systems, the EU registry under Regulation (EU) No 528/2012 and a national registry under transitional measures that coexist. Under Regulation (EU) No 528/2012, there are 14 products for product type 18 (insecticides) and 20 for product type 8 (wood preservatives). Under Transitional measures, there are 189 products authorized as insecticides and one product as wood preservatives that contain cypermethrin.

46. Additional information was also provided by **Lithuania**, the **Netherlands** (in Dutch), **Portugal** and **Sweden** on authorised biocidal products or plant protection products that have as an active substance cypermethrin in the composition.

47. **Kuwait:** a restricted pesticide (cypermethrin 10% EC) for baits and traps has been registered for only one company and no quantity has been imported so far.

48. **New Zealand:** cypermethrin is currently listed on the Environmental Protection Authority Priority Chemical List (PCL) and is one of 11 synthetic pyrethroids currently under reassessment after grounds for a reassessment application was decided in 2018. There are two substances containing cypermethrin 10% (approval numbers HSR001755 and HSR001771).

49. The controls imposed on cypermethrin EC 10 (HSR001755) include "Requirements for protective clothing and equipment" as follows; Protective clothing/equipment must be employed when cypermethrin EC 10% is being handled. The clothing/equipment must be designed, constructed and operated to ensure that the person does not come into contact with the substance and is not directly exposed to a concentration of the substance that is greater than the Workplace Exposure Standard (WES) for that substance. The person in charge must ensure that people using the protective clothing/equipment have access to sufficient information specifying how the clothing/equipment may be used, and the requirements for maintaining the clothing/equipment.

50. **Norway:** cypermethrin is currently not approved in any plant protection products in Norway. A previous approval of a product containing 100 g Cypermethrin /l (Ripcord), expired 31.12.1995.

51. **Oman:** Oman has registered six products containing cypermethrin 10% EC and all are restricted according to MD160/2023 for veterinary use only. The Material Safety Data Sheet for Vetarin EC10 (10% cypermethrin) has the following information on hazard identification through SKIN CONTACT:

52. Short single exposure may cause skin irritation. Prolonged or repeated exposure may cause severe skin irritation.

53. **Switzerland:** cypermethrin is included in Annex 1 of the Plant Protection Products Ordinance, which lists the active substances authorized in Switzerland. The following plant protection products (PPPs) containing cypermethrin are currently authorized: cypermethrin 47,5% EC, **cypermethrin 11% EC**, cypermethrin 0.96% ME, cypermethrin 0.0055% AL, cypermethrin 10.2% EW, cypermethrin 7.89 % and piperonyl butoxide 22.5% EC, cypermethrin 2.24% and piperonyl butoxide 6.34% UL1. Between 1 January 1995 and 31 December 2022, the Swiss poison information centre Tox Info Suisse documented 227 cases (80 children among them) of human intoxication or suspected intoxication by cypermethrin (excluding alpha-cypermethrin). Of these, 22 cases occurred in an occupational setting.

54. In Switzerland, the use of plant protection products is subject to authorization in accordance with the Ordinance of 18 May 2005 on the Reduction of Risks relating to the Use of Certain Particularly Dangerous Substances, Preparations and Articles (Chemical Risk Reduction Ordinance). The use of plant protection products and pesticides on behalf of third parties may only be carried out on a professional or commercial basis by natural persons holding a permit, or qualifications recognized as equivalent, or under their direction. The permit is issued to anyone who has passed an examination demonstrating that they have the necessary knowledge to use PPPs, particularly in the areas of ecology, toxicology, disposal of PPPs and measures to protect human health and the environment, as well as knowledge of legislation on the protection of the environment, health and workers. No registered uses have been identified in Switzerland for watermelon, cucumber and maize.

55. Data specifically for the cypermethrin 10% EC are not available, but cases involving products containing the active substance cypermethrin were reported. Between 1 January 1995 and 31 December 2022, Tox Info Suisse documented 227 cases (80 children among them) of human intoxication or suspected intoxication to cypermethrin (excluding alpha-cypermethrin). The product was ingested orally in 62 cases, inhaled in 83 cases, dermally in 39 cases, ocularly in 29 cases and by other or combined means in 14 cases. While 210 cases were accidental, 16 cases were intentional (suicidal, abusive, other intentional exposures) and one case was in an unknown context. Of the accidental cases, 22 occurred in an occupational setting, while 168 cases occurred in a domestic setting. Three cases were classified as environmental, and a further 17 cases could not be assigned to any of these categories. Of the 24 cases for which Tox Info Suisse received medical feedback, two cases had no symptoms, 19 cases had mild symptoms and three cases had moderate symptoms. Of these, three mild cases were occupational. For two of these occupational cases the products contained cypermethrin and one other active substance (piperonyl butoxide or chlorpyrifos). The third case was relevant for cypermethrin only.

56. In summary and based on the above, it can be concluded that a safe use of pesticide formulations containing cypermethrin, including cypermethrin 10% EC, is only possible when a number of protective measures are applied.

57. Therefore, the incidents reported from Lao PDR are considered relevant to other States or regions, and this criterion is considered to be met.

(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;

58. The survey of 2019 indicates that cypermethrin is not registered in the country for pesticide use, including on this particular applications and crops (watermelon, cucumber and maize). Accordingly, Part A submission of the Party indicates that no handling or applicator restriction exist as a condition of a national registration of the pesticide formulation in question. In the incident reported with **Super PHONEWDOL 10**, the farmers used a hand-held battery-operated sprayer at a dose of 15 or 30ml/20 L water and PPE comprising of gloves, boots/shoes, long sleeve shirt, long pants and simple hat. The label (in Thai) recommended use of gloves and mask during handling of pesticide.

59. As regards the pesticide application technology used in Lao PDR, farmers who have small plantation area (0.2- 0.3 ha) used either motorized or hand-operated knapsack sprayers or hand-held battery-operated sprayer with 20 L capacity. Farmers who have larger farm areas or big plantation areas usually used mini tank-mounted tractors (banana, maize) for spraying.

60. The use of proper PPE among farmers during pesticide handling is not common. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pants, head cover, face cover and shoes). The reasons why farmers do not wear full PPE such as coveralls, eye glasses or goggles, rubber mask with filter etc., were the hot weather conditions and unavailability of PPE at an affordable cost.

61. On the other hand, a number of parties have provided information on the existence of handling or applicator restrictions for registered uses of cypermethrin-containing pesticides, namely from Canada, Switzerland, Germany and New Zealand (see para (b) above). These restrictions are communicated via the products label and may include instructions for the use of baseline personal protective equipment (long pants, long-sleeved shirt and chemical-resistant gloves) for all uses except for mechanically pressurized handgun application to specific crop when additional personal protective equipment (cotton coveralls) was considered, etc.

62. Information provided by the Parties above shows that products containing cypermethrin are unlikely to affect human health if used according to the directions on the label. Accordingly, the information provided on the common use of minimum PPE and application technology in Lao PDR, and the practices carried out with the use of cypermethrin 10% EC are also relevant for the three reported incidents in this proposal.

63. Based on the above, this criterion appears to be met.

(d) The significance of reported effects in relation to the quantity of the formulation used;

64. The 2019 survey in Lao PDR found that pesticides with the active ingredient cypermethrin are among the most widely used in agricultural crops. Cypermethrin was among the common insecticides used (maize, cucumber and watermelon). The use of certain pesticide formulations under the local conditions had caused adverse effects to the farmers. Cypermethrin 10% EC was among the pesticides that has been reported by farmers to cause poisonings.

65. While the report from the survey suggests that “in cases of serious poisonings, farmers would seek medical treatment from the government hospital (p7, section 4.2.9), the incident reports (Part B form) indicate that no medical treatment/hospitalization have been given in two of three cases for the recovery of the patient. In the third incident report, medicine was bought from pharmacy.

66. For cypermethrin 10% EC, the three incident reports relate to non-registered applications of the pesticide to maize, cucumber or watermelon at an average rate of 15-30ml/20 L of water (lower dose than label recommendation) using a hand-held sprayer in the field for half day period/ > 4 hours.

67. As for the types of symptoms recorded, farmers reported a range of poisoning symptoms due to pesticide exposure, and some of the symptoms are very generic in nature while others are typical symptoms of pesticide poisonings. The symptoms that occurred in 4-12 hours after exposure with cypermethrin 10% EC were ***excessive sweating, itchiness of the skin, cough, and insomnia.*** The reversibility of the symptoms is not reported (e.g., duration in hours or days).

68. Cypermethrin is considered to be slight eye and skin irritant by Canada. According to the Label Amendments for products containing cypermethrin in Canada the statement “Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically” is to be added to the label. The evaluation by Canada supports that dermal symptoms like itchiness of the skin may occur if skin is exposed, and that this symptom is transient. Information provided from Oman on

a product containing 10% cypermethrin also reports that short single exposure may cause skin irritation and that prolonged or repeated exposure may cause severe skin irritation.

69. All incidents with cypermethrin reported to the Swiss Poison centre were assigned as “mild”. For the occupational incident relevant for cypermethrin only, cough was reported as a symptom after exposure through inhalation: “A 45-year-old farmer was sprayed in the face with a product containing cypermethrin and inhaled the fumes. He immediately felt a burning sensation on his lips. He later developed a chesty cough and dyspnea on exertion. The man was symptom-free after 3 days. Severity: mild.”

70. In Germany, 68 poisoning cases involving cypermethrin are recorded, and most were assigned as “minor or moderate” in the German national register on human poisonings with chemicals at BfR in the period 1990-2023. Two poisoning cases were “severe”, but they were not considered relevant for cypermethrin 10% EC (one of the incidents in Germany was with intravenously exposure which ended-up with death and the other was a suicidal attempt through oral exposure; document 4183-attachment 2_cypermethrin_DE). However, there is no information on the active concentration of cypermethrin in these formulations.

71. In Canada and the USA (incidents are not expressed by formulation type): as of 17 September 2015, there were seven human and 22 domestic animal incident reports in the PMRA database involving the active ingredient cypermethrin. There was a low degree of association between the reported effects and exposure to the pesticide in the human incidents, and some degree of association in the domestic animal incidents. In one human incident report, symptoms were consistent with effects reported in the literature. This incident occurred in Canada, and the subject experienced minor dermal symptoms following accidental contact with a contaminated glove. All but one of the domestic animal incidents occurred in the US; the Canadian incident was of minor severity.

72. In summary, it can be assumed that the symptoms reported in the three incidents are caused by exposure to cypermethrin 10% EC. Considering the information provided from other countries, health effects observed within a short period of time after exposure reveal that skin irritation and cough were some of the symptoms of exposure to cypermethrin.

73. Based on the incidents reported in Lao PDR from the use of the proposed SHPF **cypermethrin 10% EC** concerning the lower quantity of the formulation used for a long time period (half a day/ > 4 hours) and the recommended dosage in the label this criterion appears to be met.

(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

74. The reason for the proposal by Lao PDR to list cypermethrin 10% EC as a SHPF in Annex III is due to acute pesticide poisoning incidents caused by occupational exposure of operators during the application in the field and/or mixing/loading under common conditions of use for pest control. Intoxication from intentional misuse was not reported as a reason for the proposal.

75. Therefore, this criterion is considered to be met.

II. Conclusion

76. The Task Group concluded that the proposal from Lao PDR to list cypermethrin 10% EC in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Part 1 of Annex IV, meets criteria set out in Part 3 of Annex IV of the Convention, taking into account the information collected by the Secretariat according to Part 2 of Annex IV.

VIII. Task group report on cypermethrin emulsifiable concentrate 35%

Rotterdam Convention

Twentieth meeting of the Chemical Review Committee

Rome, Italy, 17–20 September 2024

Report of the task group on cypermethrin emulsifiable concentrate 35%

Task group members

Chair Suzana Andrejevic Stefanovic (Serbia)

Drafter Irene Beate Sørvik Malme (Norway)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/25 : Cypermethrin emulsifiable concentrate 35%

UNEP/FAO/RC/CRC.20/INF/48: Cypermethrin emulsifiable concentrate 35%: information collected by the Secretariat

Introduction

1. A proposal from the Lao People's Democratic Republic to list cypermethrin emulsifiable concentrate 35% in Annex III to the Convention as a severely hazardous pesticide formulation was available to the Committee together with supporting documentation from this country. The proposal has undergone an initial review by the Secretariat, who concluded that the proposal did appear to meet the information requirements of part I of Annex IV to the Convention (UNEP/FAO/RC/CRC.20/25).

2. As laid down in Article 6 of the Convention, the Secretariat forwarded a summary of the information received to all parties and collected additional information as specified in part 2 of Annex IV. This information is available in documents UNEP/FAO/RC/CRC.20/INF/48.

3. The purpose of this report is to present the task group’s analysis of the proposal from the Lao People's Democratic Republic together with the supporting documentation for the Committee’s consideration.

4. The report includes a summary of the background of the proposal, a summary of the documentation required according to Annex IV, part 1, a summary of the availability of information that was collected by the Secretariat according to part 2 of Annex IV (tabular format) and an analysis of compatibility with the criteria of Annex IV part 3 (tabular summary and detailed analysis).

5. The report contains an overall analysis.

I. Analysis of the proposal from the Lao People's Democratic Republic

A. Background of the proposal

6. Within the Rotterdam Convention project on monitoring pesticide survey on Highly Hazardous Pesticides (HHPs) and Severely Hazardous Pesticides (SHPFs) conducted in Lao People's Democratic Republic (Lao PDR) in the period from January 2019 to May 2020, a field monitoring survey was carried out in 25 villages of 10 districts in three provinces in June-July 2019. A total of 169 farmers participated. The farmers were predominately males and most had a secondary/high school level education.

7. All pesticides produced, imported, exported, distributed and used in Lao PDR, must be registered with the Department of Agriculture, Ministry of Agriculture and Forestry, in accordance with Regulation on the Control of Pesticides in Lao PDR (No. 2860/MAF, Vientiane Capital, dated 11 Jun 2010). The survey showed, however, that the use of illegal pesticide products is widespread and that pesticides illegally imported and bought from unlicensed shops are still a common practice in the provinces. Also, the use of banned products is a problem in Lao PDR.

8. A total of 40 pesticide products were used by the farmers (active ingredients of different product names i.e. 22 insecticides, 12 herbicides and 6 fungicides), but only four of these products were registered with label in Lao language. The rest of the 36 products were illegally traded unregistered or banned pesticides with labels in foreign language i.e. Thai, Vietnamese and others.

9. Farmers reported a range of poisoning symptoms due to pesticide exposure. Some of the symptoms were very generic in nature while others were typical symptoms of pesticide poisoning. Lao PDR does not have a reporting system for incidents of pesticide poisoning. Three of these incidents were reported to be caused by using one of the unregistered products FRONK 35 labelled in Thai (cypermethrin 35% EC), a synthetic pyrethroid insecticide. The product was used with a hand-held battery-operated sprayer at a dose of 1500 ml/ha or 30 ml/20 L water. For two of the incidents, adverse effects reported were itchiness of the skin, headache, and excessive sweating after application in the field for half day period on maize and cucumber. For the third incident, spraying application for half day period in maize caused itchiness of the skin and skin rashes. The symptoms in the first two incidents were not medically treated while the third incident were treated with medicine from pharmacy. In all three incidents the operators were male, age 20-60* using protective clothing comprising gloves, boots/shoes, long-sleeve shirt and long pants (*the age in the third incident was not reported). The symptoms occurred within 4-12 hours after using the pesticide.

10. The field monitoring survey reported that in cases of serious poisonings, farmers would seek medical treatment from the government hospital whereas some farmers treated the poisonings by traditional means (drinking lemon grass tea, sniffing out ants, taking a long rest etc).

11. The use of full Personal Protective Equipment (PPE) among farmers during pesticide handling application is not common, due to hot weather and unavailability of these items at affordable cost. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers in small plantation areas, but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying.

12. The result of the implementation of the Rotterdam Convention project on monitoring pesticide survey on HHPs and SHPFs from January 2019 to May 2020 concluded that the dissemination of the decrees and legislation related to pesticide management has not been widely distributed in Lao PDR and that the accessibility of information related to pesticide rules and regulations is still limited. There is also little awareness and technical knowledge of the selection and application of pesticides among farmers. The country still does not have legal backing for taking action against illegal pesticide smuggling.

13. As a result of the monitoring, pesticide survey FRONK 35 was identified as a SHPF by Lao PDR and consequently, the Lao PDR submitted a proposal to list cypermethrin 35% emulsifiable concentrate in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

B. Summary of information provided in the proposal and analysis of its compatibility with requirements of Annex IV

Information and criteria for listing severely hazardous pesticide formulations in Annex III

1. Part 1. Documentation required from a proposing Party

(PIC Circular LVI (56) – December 2022)

(a) Name of the hazardous pesticide formulation: Cypermethrin 35% EC

(b) Name of the active ingredient or ingredients in the formulation: Cypermethrin

(c) Relative amount of each active ingredient in the formulation: 35%

(d) Type of formulation: Emulsifiable Concentrate

(e) Trade names and name of producers, if available: FRONK 35

(f) Common and recognized patterns of use of the formulation within the proposing Party:

14. The formulation is not registered in Lao PDR, hence no use was permitted. The monitoring field survey of 2019 collected information on the usage of cypermethrin 35% EC. In three occasions, the product was applied using hand-held sprayer at a dose of 30 ml/20 L of water or 1500 ml/ha for mixing/loading and spraying application on maize or cucumber. The farmers used gloves, boots, long-sleeve shirt, long pants and simple hat as PPE.

15. The field monitoring survey of 2019 describes the common and recognized pesticide application practices in the field in the Lao PDR, such as the use of illegally traded unregistered or banned pesticides with labels in foreign language (90% of the pesticides in the survey), as well as the use of partial PPE by the farmers during pesticides handling due to the high temperature or unavailability of PPE at affordable cost. The surveyed farmers reported a range of poisoning symptoms due to pesticide exposure, where some of the symptoms were very generic in nature while others were typical symptoms of pesticides poisonings.

(g) A clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used:

16. The survey in 2019 collected details on three incidents relating to FRONK 35. The incident relating to FRONK 35 can be summarized as follows: The incidents occurred after spraying the pesticides in fields where maize or cucumber was grown. The product was applied using hand-held sprayer at a dose of 30 ml/20 L of water or 1500 ml/ha. The label of the pesticide formulation (in Thai) contains information on the use (use for yard long bean, not allow to use in rice field), dosage (10 ml/20 L water), use of PPE (use of gloves and mask during handling of pesticide) and toxicity symptoms (itchy, skin rash, excessive sweating, nausea/vomiting, muscle spasms). The frequency of application is from 2 to 5 times per crop season. Symptoms occurred in 4-12 hours after exposure as itchiness of the skin, headache, excessive sweating, and skin rashes. The route of exposure was through inhalation and /or skin with the duration of half day period. Personal protective equipment such as gloves, boots, long-sleeve shirt, long pants and simple hat were used. No information is available on the date or the year of the incidents.

(h) Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents:

17. Lao People's Democratic Republic does not have a reporting system for incidents of pesticide poisoning.

18. Lao PDR decided on national risk reduction measures (legislative and non-legislative measures) as a follow up from to monitoring survey:

(a) Legislative measures:

(i) Disseminate related legislations to pesticide investors and users;

(ii) Disseminate the implementation of Rotterdam Convention to all related stakeholders; monitor the importers of pesticides by checking authorization licenses, import permits and registration certificate, records of distribution and other requirements and encourage to import tolls and plant protection equipment;

(iii) Inspect regularly retailer's shops of pesticides by checking related licenses, labelling, and record of buying and selling;

(iv) Continue to monitor pesticide use in field by extending areas and add more type of crops especially crops for export;

(v) Technique of pesticide disposal.

(b) Non-legislative measures:

(i) Strengthen training and education system on effective and judicious use of pesticide among farmers;

(ii) Disseminate related pesticide legislation for improving pesticide management system;

(iii) Train on pesticide management for pesticide inspectors at district level, taskforce team, pesticide investors, and users including pesticide applicators services;

(iv) Strengthening pesticide inspectors on updating technical knowledge related to pesticide;

(v) Training more on HHPs and SHPFs before carrying out to monitor pesticide survey;

(vi) Disseminate the implementation of RC to all related stakeholders;

(vii) Update knowledge and continue to set up pesticide inspectors at provincial and district level throughout the country;

(viii) Establish network and national database on pesticide management.

19. Current legal infrastructure/admin procedure:

(a) Ministerial Decision on Registration of Pesticides in Lao PDR No. 3604/MAF, dated 17 Sep 2019 (improvement registration scheme and advice pesticide investors to follow the decision of Registration Unit of DOA);

(b) Ministerial Decision on Using Uniform and Insignia of Pesticide Inspector No. 1232/MAF, dated 23 April 2019 (dissemination and preparation of model uniform and insignia for pesticide inspector);

(c) Ministerial Instruction on Establishment and responsibilities of Taskforce team to inspect and apply the measures to violation pesticide legislation 0278/MAF, dated 19 Feb 2020;

(d) Ministerial Decision on Control of Pesticide Businesses No.0238/MAF, dated 14 Feb 2019.

2. Part 2. Information to be collected by the Secretariat

Part 2. Information to be collected by the Secretariat		
Type of information	**Information available?**	**Documentation in:**
(a) The physico-chemical, toxicological and ecotoxicological properties of the formulation;	Yes	Information was provided by the following Parties: Australia, Canada, Brazil, Chile, European Union, Kuwait, New Zealand, Norway, Oman and Switzerland (in document UNEP/FAO/RC/CRC.20/INF/48)
(b) The existence of handling or applicator restrictions in other States;	Yes	
(c) Information on incidents related to the formulation in other States;	Yes	
(d) Information submitted by other Parties, international organizations, nongovernmental organizations or other relevant sources, whether national or international;	Yes	
(e) Risk and/or hazard evaluations, where available;	Yes	
(f) Indications, if available, of the extent of use	Yes	

Part 2. Information to be collected by the Secretariat		
Type of information	**Information available?**	**Documentation in:**
of the formulation, such as the number of registrations or production or sales quantity;		
(g) Other formulations of the pesticide in question, and incidents, if any, relating to these formulations;	Yes	
(h) Alternative pest-control practices;	Yes	
(i) Other information which the Chemical Review Committee may identify as relevant.	Yes	

3. Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III

Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III	
Criteria	**Criterion met?**
(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;	Met
(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;	Met
(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;	Met
(d) The significance of reported effects in relation to the quantity of the formulation used;	Met/Not met
(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.	Met

Compatibility with the criteria of Annex IV, part 3 - detailed argumentation

In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:

(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;

20. In Lao PDR, the field monitoring survey on pesticide practices conducted in 2019 revealed that the use of unregistered pesticides is very widespread: 36 of the pesticides recorded during the survey were unregistered pesticides while only 4 products were registered with label in Lao language. All the 36 unregistered pesticides were foreign products illegally sold in the country and the majority of them originated from Thailand (27 products), Vietnam (7 products) and 2 more from other countries. This illegal placing on the marked is possible because legal action cannot be taken against violators, since related rules/regulations not being implemented at the time of the survey. Cypermethrin, which is not registered in Lao PDR, was among the common insecticides used in the country. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers with 20 L capacity in small plantation areas (0.2-0.3 ha), but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pant, head cover, face cover and shoes). The use of full PPE like coveralls, eye protection, masks with filter etc., among farmers during pesticide handling is not common, due to hot weather and unavailability of these items at affordable cost.

21. One of the challenges faced by the surveyed farmers were the difficulty of recalling the pesticide formulations that has caused the poisonings they suffered. This was further complicated if more than one pesticide were used at the same time. Thus, 22 of the respondents reported that they had experienced some adverse effects from using certain pesticides. Still only 20 recalled the symptoms and only eight of them recalled precisely which particular pesticide product was responsible for the

symptoms they suffered from. In contrast, 12 other farmers only reported that cumulative poisoning symptoms occurred and the list of the pesticide products they used at that particular time. The use of certain pesticide formulations under local conditions has caused adverse effects to the farmers.

22. The 2019 survey collected details for 3 incidents relating to **FRONK 35** (cypermethrin 35% EC), as follows: The frequency of application was 2-5 times per crop per season. All operators (males aged 20-60 years, age was not reported in incident three) used gloves, boots/shoes, long sleeve shirt, long pants and simple hats. The label instructed to use masks and gloves when using the product. Masks and coveralls were not used, which can result in exposure through inhalation and skin when using hand-held sprayer. The type of gloves used is not specified (e.g., chemical resistant gloves). The duration of symptoms occurrence after exposure was not specified per incident. The date and year of the incidents are not stated.

23. **Incident one:** spraying the pesticide with a hand-held sprayer in the field on maize and cucumber with a dose of 1500 ml/ha. The duration of exposure was ½ day. Adverse effects occurring after 4-12 hours were itchiness of the skin, headache, and excessive sweating. The route of exposure was skin and inhalation. No treatment was given.

24. **Incident two:** the activities were mixing/loading and spraying the pesticide with a hand-held sprayer in the field on maize and cucumber with a dose of 30 ml/20 L water. The duration of exposure was ½ day. Adverse effects occurring after 4-12 hours were itchiness of the skin, headache, and excessive sweating. The route of exposure was skin and inhalation. No treatment was given.

25. **Incident three:** spraying the pesticide with a hand-held sprayer in the field on maize with a dose 30 ml/20 L water. The duration of exposure was ½ day. Adverse effects occurring after 4-12 hours were itchiness of the skin and skin rashes. The route of exposure was skin. The operator bought medicine from pharmacy, but type of medical treatment was not specified.

26. The evidence indicating that the use of **FRONK 35** (cypermethrin 35% EC), in accordance with common and recognized practices within Lao PDR, resulted in the reported incidents can be considered reliable with certain limitations (e.g. date/year of incident).

27. Based on the above, this criterion appears to be met.

(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

28. Documentation was made available to the CRC (UNEP/FAO/RC/CRC.20/INF/48) indicating that the above listed conditions for Lao PDR are similar to the conditions prevailing in other neighbouring States.

29. The same or similar formulations are used as pesticides or biocides (EU) in other countries with similar conditions. **Information was received from Australia, Brazil, Canada, Chile, the European Union, including Germany, Spain, Lithuania, the Netherlands, Portugal and Sweden, Kuwait, New Zealand, Norway, Oman and Switzerland.**

30. A summary of the available documentation regarding use of cypermethrin formulations, is presented below.

31. **Australia:** there are no registered products with 35% active concentration, and product specific handling or applicator restrictions in Australia; the number of similar registered products with the a.i. cypermethrin (**any formulation)** is 116.

32. **Brazil:** there are 24 formulated products containing cypermethrin in Brazil. Formulation based on 35% cypermethrin is not registered. Cypermethrin is a product widely used in Brazil for various crops, including: cotton, peanuts, rice, potatoes, sweet potatoes, yacon potatoes, beets, coffee, yams, carrots, citrus fruits, peas, beans, beans, chickpeas, yams, lentils, cassava, parsley, millet, corn, soybeans, sorghum and tomatoes. The product is a pyrethroid insecticide that acts through contact and ingestion on indicated biological targets which cause considerable damage to the production of the indicated crops. Currently, approximately 5.6 million hectares are treated with products formulated with cypermethrin, acting mainly on caterpillars, bedbugs, kitties and leafhoppers.

33. **Canada**: the formulations based on 35% cypermethrin emulsifiable concentrates are not registered in Canada. The following products are registered in Canada with the same or higher concentrations, and similar formulation types, to the proposed formulation: emulsifiable concentrate 407 g/L - 2 products (registration numbers 15738 and 30316) and 250 g/L – 2 products (registration number 28795 and 32563).

34. Based on the results of the risk assessment, use restrictions were included on the label to minimize the exposure to cypermethrin. Canadian handling and applicator restrictions are detailed on labels of registered Canadian products. The re-evaluation decision for cypermethrin required amendments to those handling and applicator restrictions, which are reflected on current Canadian product labels:

35. To protect mixer/loader/applicators, the following statements are proposed to be added to all agricultural product labels:

(a) Wear long-sleeved shirt, long pants and chemical-resistant gloves during mixing, loading, application, clean up and repair. In addition, wear goggles or face shield during mixing and loading.

(b) For mechanically pressurized handgun (MPHG) application to strawberry: Wear coveralls (over single layer of clothes) and chemical-resistant gloves during mixing, loading and application.

36. To protect workers entering treated sites, modified restricted-entry intervals (REI) must be added to all agricultural labels. Products containing cypermethrin are unlikely to affect your health when used according to the proposed label directions.

37. The re-evaluation decision further includes label amendments for products containing cypermethrin: The following statement is to be added to the labels of technical grade cypermethrin under the section entitled “Toxicological Information”:

Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically.

38. No registered applications have been identified for watermelon and cucumber (detected unregistered uses in Lao’s PDR).

39. **Chile:** there are no registrations or restrictions.

40. **European Union:** cypermethrin is approved for use as plant protection product and is classified as candidate for substitution. There are particular conditions to be taken into account by Member States in relation to the granting of plant protections products containing cypermethrin. Accordingly, the Review Report includes a list of restrictions that “Member States shall pay particular attention to:

(a) the protection of aquatic organisms, non-target arthropods, including bees

(b) the consumer risk assessment

(c) the technical specification of the active substance used in plant protection products

41. As pesticides for use in biocidal products, cypermethrin has been approved in the product type 08 (wood preservatives) and products type 18 (insecticides) and has 70 authorized biocidal products in the EU in the product type 08 (wood preservatives). Information on the intrinsic properties of the substance and the risk assessments performed on the active substances and the risk mitigation measures is also available.

42. Cypermethrin was not considered as skin irritant in the EU evaluation.

43. **Germany:** the active substance cypermethrin is approved at EU level for use in plant protection products (PPP). After approval of an active substance, national authorisations of the formulated PPP must be granted before placing PPP on the market. PPPs with cypermethrin are currently authorised in almost all EU Member States. PPP with the active substance cypermethrin have been authorised in Germany since 1978. As of October 2023, five different PPP with cypermethrin are authorised. 68 poisoning cases involving cypermethrin are recorded in the German national register on human poisonings with chemicals. No poisonings of vertebrates with cypermethrin have been recorded in the German national register. Information on risk reduction measures is available (in German).

44. **Spain:** there are pesticide products authorized as biocides and also as plant protection products that contain cypermethrin. As pesticides for use in agriculture, there are 19 products authorised that contain cypermethrin. As biocides, there are still two systems, the EU registry under Regulation (EU) No 528/2012 and a national registry under transitional measures that coexist. Under Regulation (EU) No 528/2012, there are 14 products for product type 18 (insecticides) and 20 for product type 8 (wood preservatives). Under Transitional measures, there are 189 products authorized as insecticides and one product as wood preservatives that contain cypermethrin.

45. Additional information was also provided by **Lithuania**, the **Netherlands** (in Dutch), **Portugal** and **Sweden** on authorised biocidal products or plant protection products that have as an active substance cypermethrin in the composition.

46. **Kuwait:** no cypermethrin 35% formulation is registered in Kuwait. A restricted pesticide for baits and traps has been registered for only one company and no quantity has been imported so far.

47. **New Zealand:** cypermethrin is currently listed on the Environmental Protection Authority Priority Chemical List (PCL) and is one of 11 synthetic pyrethroids currently under reassessment after grounds for a reassessment application was decided in 2018. There are currently no emulsifiable concentrate (EC) approvals with concentrations of 35%.

48. The controls imposed on a cypermethrin EC 10% formulation (HSR001755) include "Requirements for protective clothing and equipment" as follows; Protective clothing/equipment must be employed when cypermethrin EC 10% is being handled. The clothing/equipment must be designed, constructed and operated to ensure that the person does not come into contact with the substance and is not directly exposed to a concentration of the substances that is greater than the Workplace Exposure Standard (WES) for that substance. The person in charge must ensure that people using the protective clothing/equipment have access to sufficient information specifying how the clothing/equipment may be used, and the requirements for maintaining the clothing/equipment.

49. **Norway:** cypermethrin is currently not approved in any plant protection products in Norway. A previous approval of a product containing 100 g Cypermethrin /l (Ripcord), expired 31.12.1995.

50. **Oman:** cypermethrin 35% formulations products are not registered but has six products containing cypermethrin 10% EC. All are restricted according to MD160/2023 for veterinary use only. The Material Safety Data Sheet for Vetarin EC10 (10% cypermethrin) has the following information on hazard identification through SKIN CONTACT:

51. Short single exposure may cause skin irritation. Prolonged or repeated exposure may cause severe skin irritation.

52. **Switzerland:** cypermethrin is included in Annex 1 of the Plant Protection Products Ordinance, which lists the active substances authorized in Switzerland. The following plant protection products (PPPs) containing cypermethrin are currently authorized: cypermethrin 47.5% EC, cypermethrin 11% EC, cypermethrin 0.96% ME, cypermethrin 0.0055% AL, cypermethrin 10.2% EW, cypermethrin 7.89 % and piperonyl butoxide 22.5% EC, cypermethrin 2.24% and piperonyl butoxide 6.34% UL1. Between 1 January 1995 and 31 December 2022, the Swiss poison information centre Tox Info Suisse documented 227 cases (80 children among them) of human intoxication or suspected intoxication by cypermethrin (excluding alpha-cypermethrin). Out of the 227 cases, 22 occurred in an occupational setting.

53. In Switzerland, the use of plant protection products is subject to authorization in accordance with the Ordinance of 18 May 2005 on the Reduction of Risks relating to the Use of Certain Particularly Dangerous Substances, Preparations and Articles (Chemical Risk Reduction Ordinance). The use of plant protection products and pesticides on behalf of third parties may only be carried out on a professional or commercial basis by natural persons holding a permit, or qualifications recognized as equivalent, or under their direction. The permit is issued to anyone who has passed an examination demonstrating that they have the necessary knowledge to use PPPs, particularly in the areas of ecology, toxicology, disposal of PPPs and measures to protect human health and the environment, as well as knowledge of legislation on the protection of the environment, health and workers. No registered uses have been identified in Switzerland for watermelon, cucumber and maize.

54. Data specifically for the cypermethrin 35% EC are not available, but cases involving products containing the active substance cypermethrin were reported. Between 1 January 1995 and 31 December 2022, Tox Info Suisse documented 227 cases (80 children among them) of human intoxication or suspected intoxication to cypermethrin (excluding alpha-cypermethrin). The product was ingested orally in 62 cases, inhaled in 83 cases, dermally in 39 cases, ocularly in 29 cases and by other or combined means in 14 cases. While 210 cases were accidental, 16 cases were intentional (suicidal, abusive, other intentional exposures) and 1 case was in an unknown context. Of the accidental cases, 22 occurred in an occupational setting, while 168 cases occurred in a domestic setting. Three cases were classified as environmental, and a further 17 cases could not be assigned to any of these categories. Of the 24 cases for which Tox Info Suisse received medical feedback, two cases had no symptoms, 19 cases had mild symptoms and three cases had moderate symptoms. Of these, three mild cases were occupational. For two of these occupational cases the products contained cypermethrin and one other active substance (piperonyl butoxide or chlorpyrifos). The third case was relevant for cypermethrin only.

55. In summary and based on the above, it can be concluded that a safe use of pesticide formulations containing cypermethrin, including cypermethrin 35% EC, is only possible when a number of protective measures are applied.

56. Therefore, the incidents reported from Lao PDR are considered relevant to other States or regions, and this criterion is considered to be met.

(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;

57. The survey of 2019 indicates that cypermethrin is not registered in the country for pesticide use, including on this particular applications and crops (cucumber and maize). Accordingly, Part A of the submission of the Party indicates that no handling or applicator restrictions exist as a condition of a national registration of the pesticide formulation in question. In the incident reported with **FRONK 35**, the farmers used a hand-held battery-operated sprayer at a dose of 30 ml/20L of water to 1500 ml/ha for half day period and PPE comprising of gloves, boots/shoes, long sleeve shirt, long pants and simple hat. The label (in Thai) recommended use of gloves and mask during handling of pesticide.

58. As regards the pesticide application technology used in Lao PDR, farmers who have small plantation area (0.2- 0.3 ha) used either motorized or hand-operated knapsack sprayers or hand-held battery-operated sprayer with 20 L capacity. Farmers who have larger farm areas or big plantation areas usually used mini tank-mounted tractors (banana, maize) for spraying.

59. The use of proper PPE among farmers during pesticide handling is not common. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pants, head cover, face cover and shoes). The reasons why farmers do not wear full PPE such as coveralls, eye glasses or goggles, rubber mask with filter etc., were the hot weather conditions and unavailability of PPE at an affordable cost.

60. On the other hand, a number of parties information on the existence of handling or applicator restrictions for registered uses of cypermethrin-containing pesticides, namely from Canada, Switzerland, Germany and New Zealand (see para (b) above). These restrictions are communicated via the products label and may include instructions for the use of baseline personal protective equipment (long pants, long-sleeved shirts and chemical-resistant gloves) for all uses except for mechanically pressurized handgun application to specific crop when additional personal protective equipment (cotton coveralls) was considered, etc.

61. Information provided by the Parties above shows that products containing cypermethrin are unlikely to affect human health if used according to the directions on the label. Accordingly, the information provided on the common use of minimum PPE and application technology in Lao PDR, is also relevant for the three reported incidents in this proposal and the use of Cypermethrin 35% EC in the field on maize and cucumber.

62. Based on the above, this criterion appears to be met.

(d) The significance of reported effects in relation to the quantity of the formulation used;

63. The 2019 survey in Lao PDR found that pesticides with the active ingredient cypermethrin are among the most widely used in agricultural crops. Cypermethrin was among the common insecticides used (maize, cucumber and watermelon). The use of certain pesticide formulations under the local conditions had caused adverse effects to the farmers. Cypermethrin 35% EC was among the pesticides that has been reported by farmers to cause poisonings.

64. While the report from the survey suggests that “in cases of serious poisonings, farmers would seek medical treatment from the government hospital (p7, section 4.2.9), the incident reports (Part B form) indicate that no medical treatment/hospitalization have been given in two of three cases for the recovery of the patient. In the third incident report, medicine was bought from pharmacy.

65. For cypermethrin 35% EC, the three incident reports relate to non-registered applications of the pesticide to maize and cucumber at rate of 30 ml/20 L of water (higher dose than label recommendation) or 1500 ml/ha using a hand-held sprayer in the field for half day period.

66. As for the types of symptoms recorded, farmers reported a range of poisoning symptoms due to pesticide exposure, and some of the symptoms are very generic in nature while others are typical symptom of pesticides poisonings. Symptoms that occurred in 4-12 hours after exposure with cypermethrin 35% EC were: ***excessive sweating, itchiness of the skin, headache, and skin rashes.*** The reversibility of the symptoms is not reported (e.g., duration in hours or days).

67. Cypermethrin is considered to be slight eye and skin irritant by Canada. According to the Label Amendments for products containing cypermethrin in Canada the statement “Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically” is to be added to the label. The evaluation by Canada supports that dermal symptoms like itchiness of the skin may occur if skin is exposed, and that this symptom is transient. Information provided from Oman on a product containing 10% cypermethrin also reports that short single exposure may cause skin irritation and that prolonged or repeated exposure may cause severe skin irritation.

68. All incidents with cypermethrin reported to the Swiss Poison centre were assigned as “mild”. For the occupational incident relevant for cypermethrin only, cough was reported as a symptom after exposure through inhalation: “A 45-year-old farmer was sprayed in the face with a product containing cypermethrin and inhaled the fumes. He immediately felt a burning sensation on his lips. He later developed a chesty cough and dyspnea on exertion. The man was symptom-free after 3 days. Severity: mild.”

69. In Germany, 68 poisoning cases involving cypermethrin are recorded, and most were assigned as “minor or moderate” in the German national register on human poisonings with chemicals at BfR in the period 1990-2023. Two poisoning cases were “severe” but they were not considered relevant for cypermethrin 35% EC (one of the incidents in Germany was with intravenously exposure which ended-up with death and the other was a suicidal attempt through oral exposure; document 4183-attachment 2_cypermethrin_DE). However, there is no information on the active concentration of cypermethrin in these formulations.

70. In Canada and the USA (Incidents are not expressed by formulation type): As of 17 September 2015, there were seven human and 22 domestic animal incident reports in the PMRA database involving the active ingredient cypermethrin. There was a low degree of association between the reported effects and exposure to the pesticide in the human incidents, and some degree of association in the domestic animal incidents. In one human incident report, symptoms were consistent with effects reported in the literature. This incident occurred in Canada, and the subject experienced minor dermal symptoms following accidental contact with a contaminated glove. All but one of the domestic animal incidents occurred in the US; the Canadian incident was of minor severity.

71. In summary, it can be assumed that the symptoms reported in the three incidents are caused by exposure to cypermethrin 35% EC. Considering the information provided from other countries, health effects observed within a short period of time after exposure reveal that skin irritation may occur after exposure to cypermethrin. In addition, excessive sweating and headache were reported as symptoms after exposure to cypermethrin 35% EC.

72. Based on incidents reported in Lao PDR, it can be concluded that the farmers used **cypermethrin 35% EC** according to normal and common use patterns. Nevertheless, concerning the higher quantity of the formulation used for a long time period (half a day) and the recommended dosage in the label, this criterion appears [not] to be met.

(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

73. The reason for the proposal by Lao PDR to list cypermethrin 35% EC as a SHPF in Annex III is due to acute pesticide poisoning incidents caused by occupational exposure of operators during the application in the field and/or mixing/loading under common conditions of use for pest control. Intoxication from intentional misuse was not reported as a reason for the proposal.

74. Therefore, this criterion is considered to be met.

II. Conclusion

75. The Task Group concluded that the proposal from Lao PDR to list cypermethrin 35% EC in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Part 1 of Annex IV, [does not] meet criteria set out in Part 3 of Annex IV of the Convention, taking into account the information collected by the Secretariat according to Part 2 of Annex IV.

IX. Task group report on emamectin benzoate water soluble granules 5%

Rotterdam Convention

Twentieth meeting of the Chemical Review Committee

Rome, Italy, 17–20 September 2024

Report of the task group on emamectin benzoate water soluble granules 5%

Task group members

Chair Suzana Andrejevic Stefanovic (Serbia)

Drafter Irene Beate Sørvik Malme (Norway)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/26: Emamectin benzoate water soluble granules 5%

UNEP/FAO/RC/CRC.20/INF/49: Emamectin benzoate water soluble granules 5%: information collected by the Secretariat

Introduction

1. A proposal from the Lao People's Democratic Republic to list emamectin benzoate water soluble granular 5% in Annex III to the Convention as a severely hazardous pesticide formulation was available to the Committee together with supporting documentation from this country. The proposal has undergone an initial review by the Secretariat, who concluded that the proposal did appear to meet the information requirements of part I of Annex IV to the Convention (UNEP/FAO/RC/CRC.20/26).

2. As laid down in Article 6 of the Convention, the Secretariat forwarded a summary of the information received to all parties and collected additional information as specified in part 2 of Annex IV. This information is available in documents UNEP/FAO/RC/CRC.20/INF/49.

3. The purpose of this report is to present the task group's analysis of the proposal from the Lao People's Democratic Republic together with the supporting documentation for the Committee's consideration.

4. The report includes a summary of the background of the proposal, a summary of the documentation required according to Annex IV, part 1, a summary of the availability of information that was collected by the Secretariat according to part 2 of Annex IV (tabular format) and an analysis of compatibility with the criteria of Annex IV part 3 (tabular summary and detailed analysis).

5. The report contains an overall analysis.

I. Analysis of the proposal from the Lao People's Democratic Republic

A. Background of the proposal

6. Within the Rotterdam Convention project on monitoring pesticide survey on Highly Hazardous Pesticides (HHPs) and Severely Hazardous Pesticides (SHPFs) conducted in Lao People's Democratic Republic (Lao PDR) in the period from January 2019 to May 2020, a field monitoring survey was carried out in 25 villages of 10 districts in three provinces in June-July 2019. A total of 169 farmers participated. The farmers were predominately males and most had a secondary/high school level education.

7. All pesticides produced, imported, exported, distributed and used in Lao PDR, must be registered with the Department of Agriculture, Ministry of Agriculture and Forestry, in accordance with Regulation on the Control of Pesticides in Lao PDR (No. 2860/MAF, Vientiane Capital, dated 11 Jun 2010). The survey showed, however, that the use of illegal pesticide products is widespread and that pesticides illegally imported and bought from unlicensed shops are still a common practice in the provinces. Also, the use of banned products is a problem in Lao PDR.

8. A total of 40 pesticides products were used by the farmers (active ingredients of different product names i.e. 22 insecticides, 12 herbicides and 6 fungicides), but only four of these products were registered with label in Lao language. The rest of the 36 products were illegally traded unregistered or banned pesticides with labels in foreign language i.e. Thai, Vietnamese and others.

9. Farmers reported a range of poisoning symptoms due to pesticide exposure. Some of the symptoms were very generic in nature while others were typical symptoms of pesticide poisoning. Lao PDR does not have a reporting system for incidents of pesticide poisoning. One of these incidents was caused by an unregistered product SAN EMA 5 (emamectin benzoate 5% SG) labelled in Thai, an insecticide. The product was applied with a hand-held battery-operated sprayer at a rate of 15 g/20L water. The adverse effects reported were itchiness of the skin and skin rashes after application in the field for half day period on maize. The operator was a male, aged >60 years using protective clothing comprising gloves, boots/shoes, a long-sleeve shirt, long pants and a simple hat. The symptoms occurred after 12 hours after using the pesticide. There are other products of emamectin benzoate 5% SG registered and legally traded in Lao PDR with a label in the official language.

10. For the reported incident with SAN EMA 5, it is unknown whether the symptoms were treated. The field monitoring survey reported that in cases of serious poisonings, farmers would seek medical treatment from the government hospital whereas some farmers treated the poisonings by traditional means (drinking lemon grass tea, sniffing out ants, taking a long rest etc).

11. The use of full Personal Protective Equipment (PPE) among farmers during pesticide handling application is not common, due to hot weather and unavailability of these items at affordable cost. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers in small plantation areas, but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying.

12. The result of the implementation of the Rotterdam Convention project on monitoring pesticide survey on HHPs and SHPFs from January 2019 to May 2020 concluded that the dissemination of the decrees and legislation related to pesticide management has not been widely distributed in Lao PDR and that the accessibility of information related to pesticide rules and regulations is still limited. There is also little awareness and technical knowledge of the selection and application of pesticides among farmers. The country still does not have legal backing for taking action against illegal pesticide smuggling.

13. As a result of the monitoring pesticide survey SAN EMA 5 was identified as a SHPF by Lao PDR and consequently, the Lao PDR submitted a proposal to list emamectin benzoate water soluble granules 5% in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

B. Summary of information provided in the proposal and analysis of its compatibility with requirements of Annex IV

Information and criteria for listing severely hazardous pesticide formulations in Annex III

1. Part 1. Documentation required from a proposing Party

(PIC Circular LVI (56) – December 2022)

(a) Name of the hazardous pesticide formulation: Emamectin benzoate 5 % SG

(b) Name of the active ingredient or ingredients in the formulation: Emamectin benzoate

(c) Relative amount of each active ingredient in the formulation: 5.7 %

(d) Type of formulation: SG

(e) Trade names and name of producers, if available: SAN EMA 5

(f) Common and recognized patterns of use of the formulation within the proposing Party:

14. The product SAN EMA 5 containing emamectin benzoate 5% is not registered in Lao PDR, hence no use was permitted. However, there are other registered products containing emamectin benzoate 5% with a label in the official language. Emamectin benzoate is an avermectin class insecticide and is among one of the commonly used insecticides in Lao PDR. The information on handling or applicator restriction for the national registered products in Lao PDR (e.g., dosage, use of PPE, cultures, frequency of application) is not available.

15. The field monitoring survey of 2019 collected information on the usage of the product SAN EMA 5 (emamectin benzoate 5 % SG, labelled in Thai): the product was applied using a hand-held sprayer at a rate of 15g/20 L of water on maize. The frequency of application is about 4 times per crop season. The farmer used gloves, boots, a long-sleeve shirt, long pants and a simple hat as PPE.

16. The field monitoring survey of 2019 describes the common and recognized pesticide application practices in the field in the Lao PDR, such as the use of illegally traded unregistered or banned pesticides with labels in foreign language (90% of the pesticides in the survey), as well as the use of partial PPE by the farmers during pesticide handling due to the high temperature or unavailability of PPE at affordable cost. The surveyed farmers reported a range of poisoning symptoms due to pesticide exposure, and some of the symptoms were very generic in nature while others were typical symptoms of pesticide poisonings.

(g) A clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used:

17. The survey in 2019 collected details on one incident relating to SAN EMA 5 (emamectin benzoate 5% SG). The incident relating to SAN EMA 5 can be summarized as follows: An incident was reported (survey among farmers) involving a male age over 60. The incident occurred after spraying the pesticide in the field of maize. The product was applied using a hand-held sprayer at a dosage of 15g/20 L of water. The label of the pesticide formulation (in Thai) contains information on the use and dosage (use on Marigold flower only, 10 g/20 l water, use of gloves and mask during handling) and toxicity symptoms (itchy skin and eyes if exposure). The frequency of application was about 4 times per crop season. The symptoms of itchiness of the skin and skin rashes occurred after 12 hours from half a day exposure to the pesticide in the field. The route of exposure was through skin. It is not known whether medical treatment was given to treat the symptoms. Personal protective equipment such as gloves, boots, a long-sleeve shirt, long pants and a simple hat was used.

(h) Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents:

18. In Lao PDR, pesticide registration is product based. Since SAN EMA 5 is not registered for pesticide use in Lao PDR, its use in the country is illegal. However, there are registered products containing emamectin benzoate 5% SG with a label available in the official language.

19. As a response to the incident, reported by the monitoring survey, the responsible agencies will take appropriate actions to prevent importation and sale of unregistered pesticide products in collaboration with the Custom Department and the inspection at border check point and pesticide shops. Lao People's Democratic Republic does not have a reporting system for incidents of pesticide poisoning.

20. The responsible agencies will also create awareness and educate farmers on the danger of using unregistered/banned pesticides and disseminate information to the farmers on the availability of locally registered products containing emamectin benzoate 5 % SG.

21. Further, Lao PDR decided on national risk reduction measures (legislative and non-legislative measures) as a follow-up to the monitoring survey:

(a) Legislative measures:

(i) Disseminate related legislations to pesticide investors and users;

(ii) Disseminate the implementation of Rotterdam Convention to all related stakeholders; monitor the importers of pesticides by checking authorization licenses, import permits and registration certificate, records of distribution and other requirements and encourage to import tolls and plant protection equipment;

(iii) Inspect regularly retailer's shops of pesticides by checking related licenses, labelling, and record of buying and selling;

(iv) Continue to monitor pesticide use in field by extending areas and add more type of crops especially crops for export;

(v) Technique of pesticide disposal.

(b) Non-legislative measures:

(i) Strengthen training and education system on effective and judicious use of pesticide among farmers;

(ii) Disseminate related pesticide legislation for improving pesticide management system;

(iii) Train on pesticide management for pesticide inspectors at district level, taskforce team, pesticide investors, and users including pesticide applicators services;

(iv) Strengthening pesticide inspectors on updating technical knowledge related to pesticide;

(v) Training more on HHPs and SHPFs before carrying out to monitor pesticide survey;

(vi) Disseminate the implementation of RC to all related stakeholders;

(vii) Update knowledge and continue to set up pesticide inspectors at provincial and district level throughout the country;

(viii) Establish network and national database on pesticide management.

22. Current legal infrastructure/admin procedure:

(a) Ministerial Decision on Registration of Pesticides in Lao PDR No. 3604/MAF, dated 17 Sep 2019 (improvement registration scheme and advice pesticide investors to follow the decision of Registration Unit of DOA);

(b) Ministerial Decision on Using Uniform and Insignia of Pesticide Inspector No. 1232/MAF, dated 23 April 2019 (dissemination and preparation of model uniform and insignia for pesticide inspector);

(c) Ministerial Instruction on Establishment and responsibilities of Taskforce team to inspect and apply the measures to violation pesticide legislation 0278/MAF, dated 19 Feb 2020;

(d) Ministerial Decision on Control of Pesticide Businesses No.0238/MAF, dated 14 Feb 2019.

2. Part 2. Information to be collected by the Secretariat

Part 2. Information to be collected by the Secretariat		
Type of information	**Information available?**	**Documentation in:**
(a) The physico-chemical, toxicological and ecotoxicological properties of the formulation;	Yes	Information was provided by the following Parties: Australia, Brazil, Canada, Chile, European Union, Kuwait, New Zealand, Norway, Oman, (in document UNEP/FAO/RC/CRC.20/INF/49)
(b) The existence of handling or applicator restrictions in other States;	Yes	
(c) Information on incidents related to the formulation in other States;	Yes	
(d) Information submitted by other Parties, international organizations, nongovernmental organizations or other relevant sources, whether national or international;	Yes	
(e) Risk and/or hazard evaluations, where available;	Yes	
(f) Indications, if available, of the extent of use of the formulation, such as the number of registrations or production or sales quantity;	Yes	
(g) Other formulations of the pesticide in question, and incidents, if any, relating to these formulations;	Yes	
(h) Alternative pest-control practices;	Yes	
(i) Other information which the Chemical Review Committee may identify as relevant.	Yes	

3. Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III

Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III	
Criteria	**Criterion met?**
(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;	Met/Not Met
(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;	Met
(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;	Met
(d) The significance of reported effects in relation to the quantity of the formulation used;	Met/Not met
(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.	Met

Compatibility with the criteria of Annex IV, part 3 - detailed argumentation

In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:

(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;

23. In Lao PDR, the field monitoring survey on pesticide practices conducted in 2019 revealed that the use of unregistered pesticides is very widespread: 36 of the pesticides recorded during the survey were unregistered pesticides while only 4 products were registered with label in Lao language. All the 36 unregistered pesticides were foreign products illegally sold in the country and the majority

of them originated from Thailand (27 products), Vietnam (7 products) and 2 more from other countries. This illegal placing on the market is possible because legal action cannot be taken against violators, since related rules/regulations have not been implemented at the time of the survey. SAN EMA 5 (emamectin benzoate 5% SG) was not registered in Lao PDR and the use was therefore illegal, however there are other products containing emamectin benzoate 5% SG with a label in the official language. Hence, emamectin benzoate-containing products are among the commonly used insecticides in the country.

24. The pesticides products were generally applied with motorized or hand-operated knapsack sprayers with 20 L capacity in small plantation areas (0.2-0.3 ha), but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pant, head cover, face cover and shoes). The use of full PPE like coveralls, eye protection, mask with filter etc., among farmers during pesticide handling is not common, due to hot weather and unavailability of these items at affordable cost.

25. One of the challenges faced by the surveyed farmers were the difficulty of recalling the pesticide formulations that has caused the poisonings they suffered. This was further complicated if more than one pesticide were used at same time. Thus, 22 of the respondents reported that they had experienced some adverse effects from using certain pesticides. Still only 20 recalled the symptoms and only eight of them recalled precisely which particular pesticide product was responsible for the symptoms they suffered from. In contrast, 12 other farmers only reported the cumulative poisoning symptoms occurred and the list of the pesticides products they used at that particular time. The use of certain pesticide formulations under local conditions has caused adverse effects to the farmers. The survey reported that one of the surveyed farmers recalled the poisoning incident symptoms were due to exposure to SAN EMA 5 (emamectin benzoate 5% SG) pesticide formulation.

26. The 2019 survey collected details for one incident relating to **SAN EMA 5** (emamectin benzoate 5 % SG), as follows: The formulation was applied by spraying the pesticide with a hand-held sprayer in the field on maize with a dosage of 15g/20 L of water. The duration of exposure was ½ day. The adverse effects occurring after 12 hours were itchiness of the skin and skin rashes (toxicity symptoms described on the label are itchy skin and eyes if exposure). The route of exposure was skin. It is not known whether treatment was given. The frequency of application was about 4 times per crop per season. The farmer (male age >60 years) used gloves, boots/shoes, a long sleeve shirt, long pants and a simple hat as the PPE. Mask (recommendation on label) and coverall were not used, which can result in exposure through inhalation and skin when using a hand-held sprayer. The type of gloves used is not specified (e.g., chemical resistant gloves). The duration/reversibility of symptoms occurring after exposure was not stated.

27. The evidence indicating that the use of **SAN EMA 5** (emamectin benzoate 5 % SG), in accordance with common and recognized practices within Lao PDR, resulted in the reported incident can be considered reliable with certain limitations (e.g. only one incident was reported, whether medical treatment was given). Therefore, it is concluded that criterion (a) is [met/not met].

(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

28. Documentation was made available to the CRC (UNEP/FAO/RC/CRC.20/INF/49) indicating that the above listed conditions for Lao PDR are similar to the conditions prevailing in other neighbouring States.

29. The same or similar formulations are used as pesticides or biocides (EU) in other countries with a similar climate and conditions. **Information was received from Australia, Brazil, Chile, the European Union, including Germany, and Kuwait, New Zealand, Norway, Oman and Switzerland.**

30. A summary of the available documentation regarding use of emamectin benzoate formulations, is presented below.

31. **Australia:** there are no registered products with 5% active concentration, and product specific handling or applicator restrictions in Australia; the number of similar registered products with the a.i. emamectin benzoate (**any formulation)** is 18.

32. **Brazil:** there are three formulated products (trademarks), all 5% A.I. and Water Dispersible Granules formulation type. They are classified as Very Hazardous to the Environment – Class II – under Brazilian environmental regulations.

33. **Chile**: there are two pesticides formulated based on Emamectin benzoate 5% SG (Proclaim

050 SG and Nemesis 5 SG) with current registration. The formulations are not classified as skin irritant ("irritación cutánea; no irritante, conejos").

34. **European Union:** emamectin is approved for use as plant protection product (PPP) and is classified as candidate for substitution (because the acceptable daily intake (ADI) and acceptable operator exposure level (AOEL) for emamectin are significantly lower than the reference values of the majority of approved active substances). The substance is not allowed to be placed on the market in the EU as a biocidal product. Information on the intrinsic properties of the substance and the risk assessment performed on the active substance and the risk mitigation measures is also available.

35. It was also concluded in the "Peer review of the pesticide risk assessment of the active substance emamectin" that "Moderate or high acute toxicity is observed when emamectin is administered by the oral, dermal and inhalation routes respectively to rats. Emamectin is an eye irritant. No skin irritation was observed and there was no potential for skin sensitization". In the EU, emamectin is classified as "toxic if swallowed", "toxic in contact with skin", "toxic if inhaled" and "causes serious eye damage". Also, no case with emamectin (benzoate) as toxicologically relevant ingredients were identified in the BfR (German Federal Institute for Risk Assessment) poisoning case database.

36. Portuguese Environment Agency (apa) reports the use of emamectin benzoate (salt) 8.5 g/Kg SG, emamectin benzoate (salt) 8.3 g/Kg WG, emamectin benzoate (salt) 83.46 g/L AL and emamectin benzoate 8.3 g/Kg WG for insecticidal purpose.

37. **Germany:** no PPP containing emamectin (-benzoate) have ever been authorised in Germany; no further information is available. No poisonings of humans or vertebrates with emamectin(-benzoate) have been recorded in Germany.

38. **Kuwait:** emamectin benzoate 5 % SG is registered pesticide for insect pests, registered for only one company (no associated incidents recorded).

39. **New Zealand:** emamectin benzoate does not have an individual approval but may be used as a component of a product covered by an approval. In this regard, there are listed six substances containing emamectin benzoate 5%.

40. **Norway:** emamectin benzoate - currently not ordinary approved in any plant protection products in Norway. However, the use of a product containing 17 g/L of emamectin (Affirm) was approved for research or development purposes only on 07.05.2021. This limited permit for trial purposes only will expire 31.12.2025.

41. **Oman:** 18 products containing emamectin benzoate 5% SG are registered to use as a pesticide. There are no handling restrictions. No incidents were reported.

42. **Switzerland:** emamectin benzoate is included in Annex 1 of the Plant Protection Products Ordinance, which lists the active substances authorized in Switzerland. The following plant protection products (PPPs) containing emamectin benzoate are currently authorized: emamectin benzoate 0.95% SG and emamectin benzoate 4% ME.

43. Based on the documentation provided above, the incident reported from Lao PDR are considered relevant to other States or regions, and this criterion is considered to be met.

(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;

44. Emamectin benzoate-based pesticides is among the commonly used insecticides in the country. Since SAN EMA 5 is not registered for pesticide use in Lao PDR, its use in the country is illegal. However, there are registered products containing emamectin benzoate 5% SG with a label available in the official language. Accordingly, Part A submission of the Party indicates that no handling or applicator restrictions exist as a condition of a national registration of the pesticide formulation in question.

45. In the incident reported with **SAN EMA 5**, the farmer used a hand-held battery-operated sprayer at a dosage of 15 g/20L water and PPE comprising gloves, boots/shoes, a long-sleeve shirt, long pants and a simple hat. The label (in Thai) recommended use of gloves and mask during handling of pesticide.

46. As regards the pesticide application technology used in Lao PDR, farmers who have small plantation areas (0.2- 0.3 ha) used either motorized or hand-operated knapsack sprayers or hand-held battery-operated sprayer with 20 L capacity. Farmers who have larger farm areas or big plantation areas usually used mini tank-mounted tractors (banana, maize) for spraying.

47. The use of proper PPE among farmers during pesticides handling is not common. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pant, head cover, face cover and shoes). One of the reasons why farmers do not ware full PPE such as coveralls, eye glasses or goggles, rubber mask with filter etc., were the hot weather conditions and unavailability of PPE at an affordable cost.

48. On the other hand, some information on the existence of handling or applicator restrictions for registered uses of emamectin benzoate-containing pesticides have been provided by some parties such as the EU. These restrictions are communicated via the products label and may include instructions for the use of baseline personal protective equipment. For example, considering the different operator exposure scenarios for the outdoor use of the representative formulated product containing 0.95% emamectin benzoate (AFFIRM 095% SG) in the EU evaluation, only the mechanical downward spraying of lettuces will lead to an estimate below the AOEL without the use of personal protective equipment (e.g., use of gloves and impermeable coverall). Information is also contained in the legal act approving emamectin, the EU Review Report and in the EU risk assessment. Member States shall pay particular attention to:

(a) The risk to non-target vertebrates;

(b) The protection of workers and operators.

49. Further, in New Zealand there exists a list of controls that apply e.g., for requirements for protective clothing and equipment for a product containing emamectin benzoate (Proclaim 50 g/kg SG (HSR000110)).

50. Based on the above, this criterion seems to be met.

(d) The significance of reported effects in relation to the quantity of the formulation used;

51. The 2019 survey in Lao PDR found that pesticides with the active ingredient emamectin benzoate 5% SG are widely used in agricultural crops (maize). Emamectin benzoate 5% SG was among the commonly used insecticides in the country. Out of the 20 farmers who reported the poisoning symptoms they encountered, only 8 of them could recall which pesticide products that were responsible for the symptoms they suffered, while 12 other farmers only reported the cumulative poisoning symptoms occurred and the list of the pesticides products they used at that particular time. The use of certain pesticide formulations under the local conditions had caused adverse effects to the farmers. Emamectin benzoate 5% SG was among the pesticides that has been reported by farmers to cause poisonings.

52. For SAN EMA 5 (emamectin benzoate 5% SG), one incident with mild effects in terms of ***itchiness of the skin and skin rashes*** was reported that only relates to non-registered applications of the pesticide to maize at a rate of 15g/20 L of water (higher dose than label recommendation), using a hand-held sprayer in the field for half a day. The reversibility of the symptoms (e.g., duration in hours or days) and any information on treatments is not reported. The SAN EMA 5 product label recommends a dosage of 10 g/20 L and potential toxicity symptoms are itchy skin and eyes if exposed. Therefore, the symptoms in the reported incident are in concordance with the use of SAN EMA 5 and due to exposure of the skin.

53. The use of the formulated product SAN EMA 5 (emamectin benzoate 5% SG) can be assumed to cause the reported incident. However, no information is available regarding the use of emamectin benzoate 5% products resulting in similar incidents. The active ingredient emamectin benzoate is classified as “toxic in contact with skin” (acute toxicity category 3) in the EU but it is not regarded as a skin irritant.

54. The report from the survey suggests that “in cases of serious poisonings, farmers would seek medical treatment from the government hospital (page 7, section 4.2.9), however the incident report (Part B form) did not indicate whether medical treatment/hospitalization was given, or not.

55. Therefore, based on the incident reported from the use of the proposed SHPF emamectin benzoate 5% SG concerning the higher quantity of the formulation used for a long time period (half a day) and the recommended dosage in the label, this criterion appears [not] to be met.

(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

56. The reason for the proposal by Lao PDR to list emamectin benzoate 5% SG as a SHPF in Annex III is due to an acute pesticide poisoning incident caused by occupational exposure of an operator during the application in the field under common conditions of use for pest control. Intoxication from intentional misuse was not reported as a reason for the proposal.

57. Therefore, this criterion is considered to be met.

II. Conclusion

58. The Task Group concluded that the proposal from Lao PDR to list emamectin benzoate 5% SG in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Part 1 of Annex IV, [does not] meet criteria set out in Part 3 of Annex IV of the Convention, taking into account the information collected by the Secretariat according to Part 2 of Annex IV.

X. Task group report on methomyl soluble powder 40%

Rotterdam Convention

Twentieth meeting of the Chemical Review Committee

Rome, Italy, 17–20 September 2024

Report of the task group on methomyl soluble powder 40%

Task group members

Chair Suzana Andrejevic Stefanovic (Serbia)

Drafter Irene Beate Sørvik Malme (Norway)

Members

Observers

Secretariat

Information available to the task group

UNEP/FAO/RC/CRC.20/27: Methomyl soluble powder 40%

UNEP/FAO/RC/CRC.20/INF/50: Methomyl soluble powder 40%: information collected by the Secretariat

Introduction

1. A proposal from the Lao People's Democratic Republic to list methomyl soluble powder 40% in Annex III to the Convention as a severely hazardous pesticide formulation was available to the Committee together with supporting documentation from this country. The proposal has undergone an initial review by the Secretariat, who concluded that the proposal did appear to meet the information requirements of part I of Annex IV to the Convention (UNEP/FAO/RC/CRC.20/27).

2. As laid down in Article 6 of the Convention, the Secretariat forwarded a summary of the information received to all parties and collected additional information as specified in part 2 of Annex IV. This information is available in documents UNEP/FAO/RC/CRC.20/INF/50.

3. The purpose of this report is to present the task group’s analysis of the proposal from the Lao People's Democratic Republic together with the supporting documentation for the Committee’s consideration.

4. The report includes a summary of the background of the proposal, a summary of the documentation required according to Annex IV, part 1, a summary of the availability of information that was collected by the Secretariat according to part 2 of Annex IV (tabular format) and an analysis of compatibility with the criteria of Annex IV part 3 (tabular summary and detailed analysis).

5. The report contains an overall analysis.

I. Analysis of the proposal from the Lao People's Democratic Republic

A. Background of the proposal

6. Within the Rotterdam Convention project on monitoring pesticide survey on Highly Hazardous Pesticides (HHPs) and Severely Hazardous Pesticides (SHPFs) conducted in Lao People's Democratic Republic (Lao PDR) in the period from January 2019 to May 2020, a field monitoring survey was carried out in 25 villages of 10 districts in three provinces in June-July 2019. A total of 169 farmers participated. The farmers were predominately males and most had a secondary/high school level education.

7. All pesticides produced, imported, exported, distributed and used in Lao PDR, must be registered with the Department of Agriculture, Ministry of Agriculture and Forestry, in accordance with Regulation on the Control of Pesticides in Lao PDR (No. 2860/MAF, Vientiane Capital, dated 11 Jun 2010). The survey showed, however, that the use of illegal pesticide products is widespread and that pesticides illegally imported and bought from unlicensed shops are still a common practice in the provinces. Also, the use of banned products is a problem in Lao PDR.

8. A total of 40 pesticide products were used by the farmers (active ingredients of different product names i.e. 22 insecticides, 12 herbicides and 6 fungicides), but only four of these products were registered with label in Lao language. The rest of the 36 products were illegally traded unregistered or banned pesticides with labels in foreign language i.e. Thai, Vietnamese and others.

9. Farmers reported a range of poisoning symptoms due to pesticide exposure. Some of the symptoms were very generic in nature while others were typical symptoms of pesticide poisoning. Lao PDR does not have a reporting system for incidents of pesticide poisoning. One of the incidents were reported to be caused by using one of the unregistered products LANDERN (methomyl soluble powder 40%), an insecticide labeled in Thai. The active ingredient in the formulation, methomyl, is a carbamate insecticide with anticholinesterase activity. The product was used with a hand-held battery-operated sprayer at a dose of 30 ml/20 L water. The adverse effects occurred after application in the field of yard long bean. The symptoms were not reported. The operator was a female, aged 42 years, using protective clothing comprising gloves, boots/shoes, a long-sleeve shirt, long pants and a simple hat. The symptoms occurred more than 4 hours after the last use.

10. For the reported incident with LANDERN the symptoms were not treated. The field monitoring survey reported that in cases of serious poisonings, farmers would seek medical treatment from the government hospital whereas some farmers treated the poisonings by traditional means (drinking lemon grass tea, sniffing out ants, taking a long rest etc.).

11. The use of full Personal Protective Equipment (PPE) among farmers during pesticide handling application is not common, due to hot weather and unavailability of these items at affordable cost. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers in small plantation areas, but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying.

12. The result of the implementation of the Rotterdam Convention project on monitoring pesticide survey on HHPs and SHPFs from January 2019 to May 2020 concluded that the dissemination of the decrees and legislation related to pesticide management has not been widely distributed in Lao PDR and that the accessibility of information related to pesticide rules and regulations is still limited. There is also little awareness and technical knowledge of the selection and application of pesticides among farmers. The country still does not have legal backing for taking action against illegal pesticide smuggling.

13. As a result of the monitoring pesticide survey LANDERN was identified as a SHPF by Lao PDR and consequently, the Lao PDR submitted a proposal to list methomyl soluble powder 40% in Annex III to the Rotterdam Convention as a severely hazardous pesticide formulation.

B. Summary of information provided in the proposal and analysis of its compatibility with requirements of Annex IV

Information and criteria for listing severely hazardous pesticide formulations in Annex III

1. Part 1. Documentation required from a proposing Party

(PIC Circular LVI (56) – December 2022)

(a) Name of the hazardous pesticide formulation: Methomyl 40 % SP

(b) Name of the active ingredient or ingredients in the formulation: Methomyl

(c) Relative amount of each active ingredient in the formulation: 40 %

(d) Type of formulation: SP

(e) Trade names and name of producers, if available: LANDERN

(f) Common and recognized patterns of use of the formulation within the proposing Party:

14. The product LANDERN containing methomyl 40% is not registered in Lao PDR, hence no use was permitted. Methomyl is a carbamate insecticide with anticholinesterase activity.

15. The monitoring field survey of 2019 collected information on usage of the product LANDERN (methomyl soluble powder 40%, labelled in Thai): the product was applied using hand-held sprayer at a dose of 30ml/20 L of water on yard long bean. Frequency of application is about 5 times per crop season. For PPE, the farmer used gloves, boots, a long-sleeve shirt, long pants and a simple hat.

16. The field monitoring survey of 2019 describes the common and recognized pesticide application practices in the field in the Lao PDR, such as the use of illegally traded unregistered or banned pesticides with labels in foreign language (90% of the pesticides in the survey), as well as the use of partial PPE by the farmers during pesticides handling due to the high temperature or unavailability of PPE at affordable cost.

(g) A clear description of incidents related to the problem, including the adverse effects and the way in which the formulation was used:

17. The survey in 2019 collected details on one incident relating to LANDERN. The incident relating to LANDERN can be summarized as follows: An incident was reported (survey among farmers) involving a female aged 42 years. The incident occurred after spraying the pesticide in the field of yard long bean. The product was applied using hand-held sprayer at a dose of 30ml/20 L of water. The label of the pesticide formulation (in Thai) contains information on the use (use to control insects, pests of soybean, sorghum and peanut) and toxicity symptoms (headache, blurred vision, convulsion, staggering, excessive sweating, nausea/vomiting, excessive salivation, muscle spasms). A recommendation on the dosage and the use of PPE is not indicated on the label. The frequency of application is about 5 times per crop season. Symptoms occurred in 4-12 hours after exposure. However, the symptoms were not reported. The route of exposure was through inhalation with a duration of less than 4 hours. Medical treatment was not given to treat the symptoms. Personal protective equipment such as gloves, boots, a long-sleeve shirt, long pants and a simple hat was used. No information is available on the date or year of the incident.

(h) Any regulatory, administrative or other measure taken, or intended to be taken, by the proposing Party in response to such incidents:

18. Since products containing methomyl are not registered in Laos, its usage in the country is illegal. The responsible agencies will take appropriate actions in collaboration with the Customs Department, the inspection at border check point and pesticide shops, to prevent the importation and sale of unregistered pesticide products (including methomyl).

19. The responsible agencies will also create awareness and educate farmers on the danger of using unregistered/banned pesticides and disseminate information to the farmers on the availability of suitable locally registered alternatives to methomyl.

20. Lao People's Democratic Republic does not have a reporting system for incidents of pesticide poisoning.

21. Lao PDR decided on national risk reduction measures (legislative and non-legislative measures) as a follow-up from the monitoring survey:

(a) Legislative measures:

(i) Disseminate related legislations to pesticide investors and users;

(ii) Disseminate the implementation of Rotterdam Convention to all related stakeholders; monitor the importers of pesticides by checking authorization licenses, import permits and registration certificate, records of distribution and other requirements and encourage to import tolls and plant protection equipment;

(iii) Inspect regularly retailer's shops of pesticides by checking related licenses, labelling, and record of buying and selling;

(iv) Continue to monitor pesticide use in field by extending areas and add more type of crops especially crops for export;

(v) Technique of pesticide disposal.

(b) Non-legislative measures:

(i) Strengthen training and education system on effective and judicious use of pesticide among farmers;

(ii) Disseminate related pesticide legislation for improving pesticide management system;

(iii) Train on pesticide management for pesticide inspectors at district level, taskforce team, pesticide investors, and users including pesticide applicators services;

(iv) Strengthening pesticide inspectors on updating technical knowledge related to pesticide;

(v) Training more on HHPs and SHPFs before carrying out to monitor pesticide survey;

(vi) Disseminate the implementation of RC to all related stakeholders;

(vii) Update knowledge and continue to set up pesticide inspectors at provincial and district level throughout the country;

(viii) Establish network and national database on pesticide management.

22. Current legal infrastructure/admin procedure:

(a) Ministerial Decision on Registration of Pesticides in Lao PDR No. 3604/MAF, dated 17 Sep 2019 (improvement registration scheme and advice pesticide investors to follow the decision of Registration Unit of DOA);

(b) Ministerial Decision on Using Uniform and Insignia of Pesticide Inspector No. 1232/MAF, dated 23 April 2019 (dissemination and preparation of model uniform and insignia for pesticide inspector);

(c) Ministerial Instruction on Establishment and responsibilities of Taskforce team to inspect and apply the measures to violation pesticide legislation 0278/MAF, dated 19 Feb 2020;

(d) Ministerial Decision on Control of Pesticide Businesses No.0238/MAF, dated 14 Feb 2019.

2. Part 2. Information to be collected by the Secretariat

Part 2. Information to be collected by the Secretariat		
Type of information	**Information available?**	**Documentation in:**
(a) The physico-chemical, toxicological and ecotoxicological properties of the formulation;	Yes	Information was provided by the following Parties: Australia, Canada, Brazil, Chile, European Union, Kuwait, New Zealand, Norway, Oman, and Switzerland (in document UNEP/FAO/RC/CRC.20/INF/50)
(b) The existence of handling or applicator restrictions in other States;	Yes	
(c) Information on incidents related to the formulation in other States;	Yes	

Part 2. Information to be collected by the Secretariat		
Type of information	**Information available?**	**Documentation in:**
(d) Information submitted by other Parties, international organizations, nongovernmental organizations or other relevant sources, whether national or international;	Yes	
(e) Risk and/or hazard evaluations, where available;	Yes	
(f) Indications, if available, of the extent of use of the formulation, such as the number of registrations or production or sales quantity;	Yes	
(g) Other formulations of the pesticide in question, and incidents, if any, relating to these formulations;	Yes	
(h) Alternative pest-control practices;	Yes	
(i) Other information which the Chemical Review Committee may identify as relevant.	Yes	

3. Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III

Part 3. Criteria for listing severely hazardous pesticide formulations in Annex III	
Criteria	**Criterion met?**
(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;	Not met
(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;	Met
(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;	Met
(d) The significance of reported effects in relation to the quantity of the formulation used;	Not met
(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.	Met

Compatibility with the criteria of Annex IV, part 3 - detailed argumentation

In reviewing the proposals forwarded by the Secretariat pursuant to paragraph 5 of Article 6, the Chemical Review Committee shall take into account:

(a) The reliability of the evidence indicating that use of the formulation, in accordance with common or recognized practices within the proposing Party, resulted in the reported incidents;

23. In Lao PDR, the field monitoring survey on pesticide practices conducted in 2019 revealed that the use of unregistered pesticides is very widespread: 36 of the pesticides recorded during the survey were unregistered pesticides while only 4 products were registered with label in Lao language. All the 36 unregistered pesticides were foreign products illegally sold in the country and the majority of them originated from Thailand (27 products), Vietnam (7 products) and 2 more from other countries. This illegal placing on the market is possible because legal action cannot be taken against violators, since the related rules/regulations have not been implemented at the time of the survey. LANDERN (methomyl 40% SP) was not registered in Lao PDR and the use was therefore illegal.

24. The pesticide products were generally applied with motorized or hand-operated knapsack sprayers with 20 L capacity in small plantation areas (0.2-0.3 ha), but in larger farm areas or big plantation areas the farmers usually used mini tank-mounted tractors for spraying. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pant, head cover, face cover

and shoes). The use of full PPE like coverall, eye protection, mask with filter etc., among farmers during pesticide handling is not common, due to hot weather and unavailability of these items at an affordable cost.

25. One of the challenges faced by the surveyed farmers were the difficulty of recalling the pesticide formulations that has caused the poisonings they suffered. This was further complicated if more than one pesticide were used at the same time. Thus, 22 of the respondents reported that they had experienced some adverse effects from using certain pesticides. Still only 20 recalled the symptoms and only eight of them recalled precisely which particular pesticide product was responsible for the symptoms they suffered from. In contrast, 12 other farmers only reported that cumulative poisoning symptoms occurred and the list of the pesticide products they used at that particular time. The use of certain pesticide formulations under local conditions had caused adverse effects to the farmers.

26. The 2019 survey collected details for one incident relating to **LANDERN** (methomyl soluble powder 40%), as follows: The formulation was applied by spraying the pesticide with a hand-held sprayer in the field of yard long bean with a dose of 30ml/20 L of water. The duration of exposure was less than 4 hours. The adverse effects occurred more than 4 hours after use, but a description of the adverse effects and symptoms of intoxication are not reported. The symptoms were not treated. The route of exposure was through inhalation. The farmer (female, age 42 years) used gloves, boots/shoes, a long sleeve shirt, long pants and a simple hat as the PPE. Mask and coverall were not used, which can result in exposure through inhalation and skin when applying the pesticide with a hand-held sprayer. The frequency of application was about 5 times per crop season. The type of gloves used is not specified (e.g., chemical resistant gloves). The details about the duration /reversibility of symptoms occurring after exposure were not stated. The incident year/date was not reported.

27. The evidence indicating that the use of **LANDERN** (methomyl 40% SP), in accordance with common and recognized practices within Lao PDR, resulted in the reported incident that misses a description of the adverse effects. The symptoms of intoxication are not reported in addition to other limitations (e.g. date/year of incident). Therefore, it is concluded that criterion (a) is not met.

(b) The relevance of such incidents to other States with similar climate, conditions and patterns of use of the formulation;

28. Documentation was made available to the CRC (UNEP/FAO/RC/CRC.20/INF/50) indicating that the above listed conditions for Lao PDR are similar to the conditions prevailing in other neighbouring States.

29. The same or similar formulations are used in agriculture in countries with a similar climate and conditions, and these formulations appear to be applied with similar technology to similar crops in other countries. **Information was received from Australia, Brazil, Canada, Chile, the European Union, Kuwait, New Zealand, Norway, Oman and Switzerland.**

30. A summary of the available documentation regarding use of methomyl formulations, is presented below.

31. **Australia:** a product containing methomyl 40% as active ingredient is registered in the country with specific restrictions (withholding period: do not apply later than the number of days shown before harvest: for Brassicas: 1 day and for Grapes: 7 days. Cannot be used in covered or protected situations such as glasshouse, greenhouses or plastic tunnels, as well as in the home garden. Registered products, any formulation: 32. In Tasmania, this product must not be applied by aircraft without the specific approval of the registrar of pesticides.

32. **Brazil:** there are 24 formulated products registered in Brazil. From 2010 to 2024, an incident involving a formulation (215 g/L – active ingredient –methomyl - Concentrate (EC)) was reported, being classified as a local toxic effect. In the reported incident, the consumer was using the product and a drop of it fell into the right eye causing burning, narrowing of the pupil (miosis) and blurred vision.

33. **Canada**: the formulation proposed for listing to Annex III as Severely Hazardous Pesticide Formulation (SHPF), methomyl 40% water soluble powder is not registered in Canada. One product is registered in Canada with a higher concentration, and similar formulation type (LANNATE INSECTICIDE, 90% SP).

34. Methomyl was re-evaluated by Health Canada's Pest Management Regulatory Agency. Proposed Re-evaluation Decision PRVD2016-02, methomyl, and Final Re-evaluation Decision RVD2018-05, methomyl were published on 15 January 2016 and 29 March 2018, respectively.

35. The Final Re-evaluation Decision RVD2018-05 concluded that the most sensitive endpoint

used for risk assessment was the effect on the nervous system (decreased cholinesterase activity).

36. An evaluation of available scientific information found that some uses of methomyl products do not present unacceptable risks to human health or the environment when used according to the conditions of registration, including amended label directions. To protect the general population from dietary exposure, risk-reduction measures were required and implemented for the continued registration of methomyl in Canada.

37. In addition, certain uses of methomyl are no longer supported by the registrant and were removed from the labels.

38. Incidents were searched and reviewed for the active ingredient methomyl. As of 11 March 2014, there were six human incidents and 67 domestic animal incidents involving methomyl. All domestic animal incidents as well as four of the human incidents involved fly baits containing methomyl and (Z)-9-tricosene. The remaining two human incidents involved products containing methomyl alone.

39. **Chile:** prohibited for pesticide use in the country.

40. **European Union:** methomyl is no longer allowed to be placed on the market as plant protection product and biocidal product in the EU. A review report and a risk assessment are available, as well as information from some Member States. The review report concluded that methomyl is highly toxic via the oral, ocular and inhalation routes of exposure, but has a low toxicity via the dermal route. The most sensitive endpoint used for risk assessment was acute neurotoxicity.

41. Three poisoning cases involving methomyl are recorded in the German national register on human poisonings with chemicals, but there are no incident reports from with 40% water soluble powder formulations as methomyl 40% SP has not been authorized in Germany.

42. **Kuwait:** the pesticide is not registered in the State of Kuwait.

43. **New Zealand:** methomyl is currently being reviewed for a potential reassessment of substances containing organophosphates and carbamates used as active ingredients in a veterinary medicine or a pesticide. There are currently no approvals for water-soluble powder (SP) formulations with concentrations of 40%.

44. **Norway:** currently not approved in any plant protection product. Approval of the product Lannate was withdrawn in 1970 for toxicological reasons.

45. **Oman:** methomyl 40% SP is prohibited in Oman.

46. **Switzerland:** the placing on the market of plant protection products (PPPs) containing the active substance methomyl has been banned since 1st July 2021. Switzerland uses alternatives to methomyl against defoliating caterpillar and thrips. Water soluble powder formulations containing 25% of methomyl were authorized in Switzerland. Data specifically for the methomyl SP 40% formulation are not available, but cases involving products containing the active substance methomyl were reported. Between 1995 and 2021 126 (15 children among them) cases of human intoxication or suspected human intoxication with methomyl were documented by the Swiss poison information center Tox Info Suisse. There was medical feedback for 26 cases and among them 17 cases had no symptoms, six cases had mild symptoms, two cases had moderate symptoms and one case had severe symptoms. Of these, one moderately severe case was occupational.

47. Based on the documentation provided above, the incident reported from Lao PDR is considered relevant to other States or regions and the criterion (b) is considered to be met.

(c) The existence of handling or applicator restrictions involving technology or techniques that may not be reasonably or widely applied in States lacking the necessary infrastructure;

48. The active substance methomyl has been banned in the country for use as a pesticide for many years and there are no handling or applicator restrictions available for the specific product **LANDERN** in Lao PDR. The available label (in Thai) does not recommend specific use of PPE. Regarding the pesticide application technology used in Lao PDR, farmers who have small plantation areas (0.2- 0.3 ha) used either motorized or hand-operated knapsack sprayers or hand-held battery-operated sprayers with 20 L capacity. Farmers who have larger farm areas or big plantation areas usually used mini tank-mounted tractors (banana, maize) for spraying.

49. The use of proper PPE among farmers during pesticide handling is not common. All of the 169 farmers interviewed, used only minimum PPE (long-sleeved shirt, long pants, head cover, face cover and shoes). The reasons why farmers do not wear full PPE such as coveralls, eye glasses or goggles, rubber mask with filter etc., were the hot weather conditions and unavailability of PPE at an affordable

cost.

50. In the incident reported with **LANDERN**, the farmer used a hand-held battery-operated sprayer at a dose of 30ml/20 L of water using PPE comprising of gloves, boots/shoes, a long sleeve shirt, long pants and a simple hat. This shows that the farmer used the product methomyl 40% SP in line with the common practice and knowledge of pesticide handling and application technology that exist in Lao PDR. Due to the unavailability of label instructions for PPE use in the product label and with minor use of PPE by the user as indicated by the report, it can be assumed that the farmer was exposed to methomyl 40% SP formulation resulting in the reported poisoning incident.

51. There are existence of handling or applicator restrictions for registered uses from other parties, and the EU evaluation concluded that use of adequate PPE is necessary for methomyl-containing products to ensure operator safety and that special attention must be paid to the exposure of operator using knapsacks or other hand-held application equipment. Further, there exists an instruction for user protection (e.g., use of proper PPE for spray mixture preparation and application) for a previously registered methomyl-containing product (water-soluble powder formulation containing 25% methomyl) in Switzerland.

52. In summary, there is no information available regarding handling or applicator restrictions for the specific product LANDERN, but the information on handling or operator restrictions that is available for other products containing methomyl as active substance indicate that such restrictions are necessary to use those products safely.

53. Therefore, this criterion is considered to be met.

(d) The significance of reported effects in relation to the quantity of the formulation used;

54. The 2019 survey in Lao PDR found that pesticides with the active ingredient methomyl 40 % SP are widely used in agricultural crops and is among the common insecticides used. Methomyl 40 % SP was among the pesticides that has been reported by farmers to cause poisonings.

55. For methomyl 40 % SP, the incident report relates to illegal applications of the pesticide to yard long bean at an average rate of 30ml/20 L of water using a hand-held sprayer in the field for the period less than 4 hours. A description of the adverse effects that occurred after spray application in the field is however not reported. Based on the toxicity symptoms provided on the label (in Thai) for LANDERN, the adverse effects expected after exposure are headache, blurred vision, convulsion, staggering, excessive sweating, nausea/vomiting, excessive salivation, and muscle spasms. However, none of these effects are indicated in the incident report. It is only indicated that route of exposure was through inhalation, that the symptoms occurred after more than 4 hours, and that no treatment/hospitalization was given.

56. In Switzerland, there are details for one occupational case where exposure occurred through inhalation: “a 51-year old man applied formulations containing methomyl and spirotetramat. When the spraying device became blocked, the product ran down the man's chest, arms and legs, and he inhaled the vapors for a short time. He immediately took a shower, but shortly afterwards vomited several times. Over the next few hours, he developed dizziness, paraesthesia, miosis and moderate bradycardia. He also had mild hypokalemia. Without specific therapy, the symptoms improved within 12 hours. Severity: moderate”.

57. For the specific incident with LANDERN, the symptoms are however not reported. It is therefore not possible to conclude on the significance of the effects in relation to the quantity of the use of methomyl 40% SP (LANDERN).

58. Therefore, based on the incident reported from the use of the proposed SHPF methomyl 40 % SP in relation to the quantity of the formulation used this criterion appears not to be met.

(e) That intentional misuse is not in itself an adequate reason to list a formulation in Annex III.

59. The reason for the proposal by Lao PDR to list methomyl 40 % SP as a SHPF in Annex III is due to an acute pesticide poisoning incident caused by occupational exposure of an operator during the application in the field under common conditions of use for pest control. Intoxication from intentional misuse was not reported as a reason for the proposal.

60. Therefore, this criterion is considered to be met.

II. Conclusion

61. The Task Group concluded that the proposal from Lao PDR to list methomyl 40 % SP in Annex III to the Convention as a severely hazardous pesticide formulation met the documentation requirements of Part 1 of Annex IV, does not meet all the criteria set out in Part 3 of Annex IV of the Convention, taking into account the information collected by the Secretariat according to Part 2 of Annex IV.